Exhibit E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MASTER FILE NO. 2:12-MD-02327

MDL 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

****

****

GENERAL DEPOSITION OF SHELBY F. THAMES, Ph.D.

****

Taken at Butler Snow
1020 Highland Colony Parkway, Suite 1400,
Ridgeland, Mississippi,
on Thursday, March 24, 2016,
beginning at approximately 8:10 a.m.

****

AMY M. KEY, RPR, CSR
Notary Public

A P P E A R A N C E S

REPRESENTING THE PLAINTIFFS:

DOUGLAS C. MONSOUR, ESQ.
KATY KROTTINGER, ESQ.
Monsour Law Firm
404 North Green Street
Longview, Texas 75601
(903) 758-5757
doug@monsourlawfirm.com
katy@monsourlawfirm.com

JACOB W. PLATTENBERGER, ESQ. (Via Telephone)
Tor Hoerman Law LLC
101 West Fulton Street
Chicago, Illinois 60661
(618) 656-4400
jake@THLawyer.com

MICHAEL H. BOWMAN, ESQ.
Wexler & Wallace LLP
55 West Monroe Street, Suite 3300
Chicago, Illinois 60603
(312) 346-2222
mhb@wexlerwallace.com

SHEILA M. BOSSIER, ESQ. (Via Telephone)
Bossier & Associates, PLLC
1520 North State Street
Jackson, Mississippi 39202
601.352.5450
sbossier@bossier-law.com

REPRESENTING THE DEFENDANTS:

CHAD R. HUTCHINSON, ESQ.
Butler Snow LLP
1020 Highland Colony Parkway, Suite 1400
Ridgeland, Mississippi 39157
(601) 985-5711
chad.hutchinson@butlersnow.com

TABLE OF CONTENTS

****

E X H I B I T S

PAGE

****

****

S T I P U L A T I O N

It is hereby stipulated and agreed by respective attorneys of record, that this deposition may be taken at the time and place hereinbefore set forth, by AMY M. KEY, Court Reporter and Notary Public, pursuant to the Rules;

That the formality of reading and signing is specifically RESERVED;

That all objections, except as to the form of the questions and the responsiveness of the answers, are reserved until such time as the deposition, or any part thereof, may be used or sought to be used in evidence.

****

(EXHIBIT NO. 1 PRE-MARKED.)

SHELBY F. THAMES, Ph.D.,

having been first duly sworn,

was examined and testified as follows:

EXAMINATION

BY MR. MONSOUR:

Q. Good morning.

A. Good morning.

Q. Would you please state your name?

A. Shelby F. Thames, T-H-A-M-E-S.

Q. And, Dr. Thames, what do you do for a living?

A. I am a polymer scientist at the University of Southern Mississippi. I initially retired a few years ago, but I'm back working half time. We do research and study the area of polymers.

Q. What type of polymers would you say you specialize in?

A. Well, there are multiple types of polymers that we specialize in. There are heterocyclic type polymers in the sense that they have multiple type atoms, and then we also do work in molecules that contain, essentially, hydrogen and carbon. But, generally, I've been there long enough, I've done a lot of -- most every -- any kind of polymer we've

got.

Q. What's been marked as Exhibit 1, I think you have a copy in front of you, --

A. Yes, sir.

Q. -- is your expert report.

Do you see that?

A. I do, sir.

Q. I'm just going to read from this one. Mine has some notes on it.

But if we look at your report, it is -- it looks like it's 128 pages long; is that correct?

A. I believe so.

Q. Give me an idea, Dr. Thames, how did this report come to be?

A. I wrote it.

Q. Did you write every word of it?

A. Yes, sir.

Q. Now, if I look at it -- and you've done something which I really appreciate. I've already complimented you on your writing, but you did something else that I also appreciate. You footnoted it, --

A. Yes, sir.

Q. -- which helps me in looking at things.

A. Yes, sir.

Q. In the footnotes -- it looks like you have 344 footnotes in your report. Does that seem accurate?

A. That seems about right.

Q. In those footnotes, Dr. Thames, there are a lot of textbooks. There are a lot of articles. I think there might even be some depositions.

The question that I have is, with regard to the scientific articles or textbooks that you picked to put in here, how did you select those?

A. Well, there were specific issues that during the course of writing this report that I felt needed a reference. And there's so many people that will write and assume that whatever they write is true and accurate, and I like to reference materials as I see fit.

Q. Okay.

A. So then we begin to look for a reference, some of which I knew pretty much exactly where to go --

Q. Okay.

A. -- and others are the topical areas. So that's how I developed the bibliography.

Q. Would it be a situation where you would have an idea of, I want to write this, write it, and

then go get some sort of a footnote for support for it?

A. I know this is -- in my mind, I know this is true, but I want some verification of this in addition to what I believe so that others can read it and say, well, other people believe that too and here is reference to that work.

Q. For the articles and textbooks that you cite, do you believe that those are reliable sources that we can look to to be, you know, good, solid scientific articles and textbooks?

A. Well, for the most part, yes. We talk about peer reviewed articles, and I think some of them are really good, and I think some of them are average, and I think some of them are fairly poor.

Q. Okay. And I want to ask this in a general way without having to go through it. But if you cited an article or a textbook as authoritative in here or as a footnote, you believed it was a reliable and authoritative textbook, unless you were citing it in a way to talk about how it was incorrect. Is that a fair statement?

A. Well, I think what you're asking me, so I make sure I understand it, is that it's either pro, in response to my feelings, or not pro. And I think

there's not much in between, is there?

Q. I agree.

A. Yes, sir.

Q. So let me make sure we are on the same page because my question was kind of sloppy, as sometimes they tend to be.

If you've cited an article just as a reference and you're talking about the weaknesses of it, you're obviously not citing it as authoritative or reliable. You are criticizing it.

Fair enough?

A. Yes, sir.

Q. But when you are citing a reference for support for one of your propositions, you believe those are reliable and authoritative?

A. Yes, sir, and in the main. Yes, sir.

Q. And tell me what you mean by "in the main."

A. Well, I can't sit here as I talk to you today and remember every word or every paragraph that was in an article that I might have read two years ago or three years ago, but I wouldn't have cited it if I didn't think it was appropriate to do so.

Q. Okay. That's fair enough.

As far as your overall -- it appears to me from reading your report that most of your opinions seem to flow back to one basic premise that differs from other expert opinions in this litigation. Is that a fair statement?

MR. HUTCHINSON: Object to form.

THE WITNESS: Well, let me phrase that in a way I think of it, if you don't mind my doing that.

BY MR. MONSOUR:

Q. That's okay.

A. Obviously, the plaintiffs' experts' opinions are, in my opinion, incorrect. And they flow back to -- one simple thing for me is that Prolene is a very good polymer for its use. I believe it is about as good as you can get, as I've written in this document, for the use that it's been specified for.

It has been, in my opinion, maligned in the sense that it has been referred to as being not a good system, not fit for use, so forth. And there, in my opinion, are no solid scientific facts that support this contention.

Now, there's a lot of words and there's a lot of "I think" or "may be," but there are no solid

scientific facts that support that contention.

Q. Okay. So let's talk about -- let's talk about some of these theories. And what I was getting at -- this is -- okay. I don't talk like a polymer chemist because I'm not one. I try and talk like just a regular, everyday language kind of guy.

So my question is, the one position that it seems to me that a lot of your opinions go back and that everything seems to flow from is the issue of degradation on the surface.

You are saying that surface degradation of the Prolene does not take place. Instead, what's going on is a chemical reaction that is forming some sort of an outer layer, and that is what the other guys are seeing.

Am I close?

A. Yes, sir, very. You're getting warm, as we say.

Q. Tell me where I'm -- restate it so it's 100 percent accurate in regular people words.

A. Well, first of all, in regular people words, I think you've done a very good job.

Q. Thank you.

A. But being specific, when explants are taken in the surgery suites, almost -- I'm not

there, so I can't say 100 percent that they are. But in the vast majority of cases, they are put into formaldehyde. And that is to preserve them so that the tissue doesn't rot.

When they do that, formaldehyde is a highly reactive chemical, and it begins to react instantly with the proteins of the flesh. And the flesh is all around the explant at that time. And, in particular, collagen is surrounding the explant itself as the first coating to be applied to a Prolene explant. Because once it's in the body, collagen rushes to it, forms a layer, and then all the other body parts, the flesh, comes in and it sees collagen.

Well, collagen reacts with formaldehyde, as does the other flesh, with the proteins. If there's a protein there, formaldehyde will react with it. And it produces a hard, brittle, porous, insoluble product.

And the reason that they use formaldehyde is to, number one, preserve the flesh. But in terms of farther experimentation, if someone is going to prepare a slide for a histology, for instance, and they use a microtome -- are you familiar with a microtome?

Q. Yes, sir.

A. In order to use a microtome, they want that piece of material they're going to cut to be firm so that when they slice it across here, it doesn't do this (slaps hand over on table).

Q. Right. It's got to hold it in place.

A. It's got to hold it in place.

So the hold in place or the shield or the armor is the coating system or composite. I can call it a composite or a coating. It's a coating because it adheres tenaciously to the Prolene, and it's a composite because it's thick.

So that way, in that regard, when the microtome comes across, it holds it in the main, steady, and you can get a slice. If it doesn't do that, you can't get a 3- to 4-micron slice to make a slide from.

Q. Okay. I generally understand what you're saying. Now, I want you to understand one thing, though. When I say we have to talk like regular people, --

A. Yes, sir.

Q. -- there's four lawyers in this room.

A. Yes, sir.

Q. In order of who understands this stuff the

best, there's one and two right there (indicating). I'm not going to say which one is one and which one is two.

MR. HUTCHINSON: For the record, he pointed at defense counsel first.

BY MR. MONSOUR:

Q. There's those two over there, and then there's number three, and here is four (indicating himself).

A. Okay.

Q. And here is why today can be a little odd, because number four is asking the questions on these issues. So we're going to have to go real slow.

A. Was I too fast?

Q. No, no. You were good. I'm just kind of giving you an idea of the pecking order. So if you've talked to Chad about some stuff and he's like, "Yeah, got it, got it, got it," I'm not that way. I'm a little slower.

A. Okay.

Q. But that's okay.

A. If I can, I will go back and add to the question you asked me.

Q. Yes.

A. The plaintiffs' experts have ignored the

fact that that protein-formaldehyde layer forms and/or exists. And, as a result, I have very different opinions than they do about the chemistry that's going on. And I would quote you my by-line so that you'll know where I'm coming from for the next several days. It's all in the chemistry, period.

Q. Okay. Good, good.

Now, one of the things that you have done when I look at that, when you talk about the chemistry, you have -- I think at some point in time you have referenced some science from a long way back, from the '40s, and you've said, "Hey, this isn't new. This is back in the '40s, and here's an article," right?

A. Yes.

Q. And there's some guy who wrote it and he's got a hyphenated name, right?

A. Yes.

Q. See, I remember some stuff. Okay. So there's articles from the 1940s and --

A. '49, to be specific.

Q. 1949. And those are the articles that basically set up the chemistry, the foundation of the chemistry that your opinions flow from?

A. Well, yes, in the sense that that science has been known for 50, 66 years, and it has been ignored here. And it was developed primarily for the reason that you and I are talking about, where those individuals needed a way to look at tissue. They needed a way to make slides. And so it's been in the literature.

As a matter of fact, Dr. Lester has written a manual that's in almost all operating suites. And in that manual -- and that's referenced in my report. Susan Lester has written a manual, and in that manual she talks about the fixation process.

Now, I don't know if my lawyer is going to fuss at me about going into this lecture we're having, but this is the only way I know to try to help you understand where I'm coming from today. And that's what you want me to do, right?

Q. Yeah, yeah.

A. Fixation -- and there's another thing in chemistry. You have to listen to the words. This is called fixation. That reaction is called, by the general -- by the M.D.s and the pathologists and so forth, fixation.

What does that mean? It means holding

something in place.

Q. Okay. Got it.

A. Just like I described to you a moment ago when I talked about forming the hard shell around the fiber, I took my glass of water and put my hand around it like I'm holding this bottle of water in place.

Q. Right.

A. So the fixation process was developed to hold things in place and to preserve the flesh. I'm sure if you took high school biology you've run into contact with formaldehyde, more than likely.

So that's just been known for 60 years. Why aren't some people recognizing it in the science?

Q. Okay. Let me ask you some questions about that.

Now, your theory is our guy is not too sharp, ignoring 66 years of chemistry that these people have written about, that Dr. Lester has talked about, and it's well-known in the scientific community, right?

A. Yes, sir.

Q. Wouldn't it be a little bit of a stretch to think that all these people on our side are

missing such a basic point?

MR. HUTCHINSON: Object to form.

THE WITNESS: You know, I really don't know why they're missing it, but I do know they are, but I can't tell you why.

BY MR. MONSOUR:

Q. So let me ask -- let's go back to some of that.

Can you give me some of those articles?

MS. KROTTINGER: (Hands over documents.)

(EXHIBIT NO. 2 MARKED.)

BY MR. MONSOUR:

Q. So, Dr. Thames, I'm going to mark this as Exhibit No. 2. Your report was 1. Here's Exhibit No. 2. I think this is one of the articles you cite. And I was right. There's a hyphen. It's Heinz Fraenkel-Conrat. There's the spelling.

And it's an article, "The Reaction of Formaldehyde with Proteins," and this is part 7. I think this is the one you cite. I don't know if I have an extra one.

Is that the one you're talking about?

And here's another one I'll show you, Dr. Thames. This one is No. 3.

(EXHIBIT NO. 3 MARKED.)

BY MR. MONSOUR:

Q. This is one that kind of, in my mind, speaks -- or at least in her mind speaks a little more specifically. It's another one of the articles in a series of this, Exhibit 3. It's written by the same author, Fraenkel-Conrat.

A. Yeah, sure. Both of these articles speak to the science that I'm referring to.

Q. So here's one of the questions that I have. In your report on page 17, you have an equation. And that equation explains what you're talking about, correct?

A. Yes, sir.

Q. And you got it from Fraenkel-Conrat, as you have referenced?

A. Well, that -- I put that together. I used his science to reference it. But as a polymer scientist, I've known this reaction occurred for years. So I put it together myself based on the science I understand and know and as referenced by these papers.

Q. So if you look at the equation that you have on page 17 of your report, basically what it shows is it's a protein plus a formaldehyde goes to create this cross-linked protein-formaldehyde

polymer, correct?

A. Yes, sir. And this is just one example. This is from an amide functional hydrogen. There can be amines that are there. This is just to give you an overall view of this equation. But it's amines or amide functionality that cross-link with formaldehyde to give you the condensed polymer and the formation of the hard shell.

Q. And I guess what I'm getting at is, if you look in these articles, they actually call it pretty much the same -- they refer to it as a cross-linking in the 1948 or '49 article, correct?

A. Yes, sir.

Q. And that's what you're referring to it as, correct?

A. Yes, sir.

Q. Now, one of the questions that -- if we look at this group, it talks about to have this chemical reaction take place, you need to have the proteins, the formaldehydes, but you need to have -- one of the things that's necessary is an amino group. That's talked about in the article, correct?

A. Yes.

Q. But you don't have an amino group in your equation.

A. This is an amide group, which is the derivative that I just stated. But there are also amino group functionalities in the proteins. Those groups will react exactly the same way as this amide type functionality that I've shown you.

Q. But I guess my question is, is your cross-linking that you have, is this that you're explaining here, is this -- is there anything with your equation that's different than what Dr. Fraenkel-Conrat was talking about 66 years ago?

Are you pretty much directly on point with him?

A. Yes, sir.

Q. All right. And has this chemistry ever changed?

A. No, sir.

Q. Chemistry is chemistry is chemistry is chemistry?

A. That's it.

Q. Now, one of the things that you have talked about is the strength of this cross-linked -- you call it a --

MR. MONSOUR: Hold on. I want to get him and I on the same page.

BY MR. MONSOUR:

Q. What you're calling -- see, she wants to tell me it's a methylene-something group.

A. She's right.

Q. She might as well be speaking Chinese to me. I don't know what that is. I'm going to call it the stuff on the outside.

As far as the stuff that's on the outside, basically what you're saying is that's not degraded polypropylene. That's not degraded Prolene. That is this protein-formaldehyde mixture/combination that forms this cross-linked protein-formaldehyde polymer, right?

A. In your terminology, yes. This is the composite, the material that's formed around the fiber by virtue of formaldehyde reacting with proteins.

Q. Now, in the literature -- and you have referenced -- you've said this is the science. This has been the science for 66 years. We've known it. And probably, in truth, they knew it before this.

The question that I have is, since that time, over time, has there been a known way to clean these pieces of polypropylene, or whatever this cross-linked polymer forms on, so that we can look at the underlying prosthesis?

A. The material that I read -- and people have tried a variety of techniques. The proposition that I was faced with is you have these explants. You want to look at the explants, and you do not want to harm them. And "them" being the fiber. When I say an "explant," I'm primarily talking about fiber, okay, the Prolene fiber. You don't want to harm that so that when you finally do get everything removed from the fiber you haven't damaged it in the process of doing that.

Q. Okay.

A. So the approach that we took in cleaning this was one which -- it goes back to this equation that you're pointing out on page 17.

Q. Okay.

A. If you'll notice, this equation, it shows the protein plus the formaldehyde. And, normally, in a chemical reaction you'll have a yields sign with an arrow pointing in one direction. But if you notice something about these arrows, they go in both directions, meaning that is an equilibrium reaction.

So you've got -- assume that this one arrow is going in both directions, as it shows here. So if I want to clean this material and I want to get back to the fiber that's encased by this product

right here, and I'm pointing to the protein and the formaldehyde composite that would form, then I would add water and heat and the reaction reverses.

And so I've taken a very mild set of circumstances chemically speaking, reversed the reaction, used a little sodium hypochlorite to get rid of some of the flesh to get to a fiber that is as pristine, in my view, as you could ever have coming from -- as an explant to be analyzed.

So I have an explant that has not been damaged in any way. And what I look at is what was there in the body.

Q. But if I look at your cleaning protocol, it seems like there's a lot more steps involved than just a little water and a little heat.

A. Oh, there is. The steps are there to ensure that we ultimately get all the material off the explant. It's very difficult. Because the adhesion that takes place between the proteins and the explant itself is tenacious. It's a very strong bond.

So we've got to break through that crust of composite material. We've got to break through the armor and finally get to remove all of the proteins, if that's possible.

Q. So in light of the fact that this bond that forms is so tenacious, would the tenacity of such a bond have been known to scientists for decades?

MR. HUTCHINSON: Object to form.

THE WITNESS: It should have been.

BY MR. MONSOUR:

Q. And the reason -- I'm going to ask you a few questions that sound kind of like state-of-mind questions. But you've told me that our people have ignored it, which is kind of a state-of-mind comment, so I'm going to kind of come back with a few state-of-mind questions.

A. Sure.

Q. Whether they're admissible or not, who knows?

But my point is, was it well understood in the scientific community, in your opinion, that these bonds were tenacious?

A. Yes, sir.

Q. And was it well known that you had to take that into account when you were cleaning prosthesis that would have this coating, this cross-linked protein-formaldehyde polymer coating on top of it?

MR. HUTCHINSON: Object to form.

THE WITNESS: Would you restate that, please?

BY MR. MONSOUR:

Q. Yeah. Was it well known in the scientific community that when cleaning the cross-linked protein-formaldehyde polymer that would form on the outside, that you would need to take into account the tenacity in order to get -- to remove everything that had formed on the outside of an implant?

MR. HUTCHINSON: Same objection.

THE WITNESS: It should have been.

BY MR. MONSOUR:

Q. So what you're saying is basically, as I understand it, what you're saying is, "I'm the mainstream guy here. I'm looking at all this -- everything I'm telling you has been known for six-and-a-half decades. You guys have just ignored it," right?

A. Well, either they ignored it or they didn't know about it. I mean, I don't know what they -- I don't know why they don't talk about it, but that's the case. It's irrefutable that this happens.

Q. But I guess my point is, I mean, if you're telling me this is common knowledge and it's well

known -- and you've got two articles here from the '40s. And it looks like it's a series of at least seven, so this isn't something that came out two weeks ago. If it's so well known, how could so many scientists have missed it?

MR. HUTCHINSON: Form.

THE WITNESS: Well, a lot of people have missed it, and I believe that's because they aren't looking at the fundamental chemistry. And the people who have been looking at this particular issue are not necessarily chemists. A lot of them have medical backgrounds. A lot of them are engineers. And they may not be that well versed in basic organic chemistry.

BY MR. MONSOUR:

Q. Do you know Dr. Jimmy Mayes?

A. I do.

Q. Do you know him well?

A. Well, I would say, yes, I know him pretty well.

Q. He's pretty competent in chemistry, wouldn't you say?

A. I would definitely say so.

Q. He's a nice guy, wouldn't you agree?

A. Absolutely. I like him.

Q. One of the questions that I would like to go over with you is, in light of the fact that this bond, the tenacious bond that forms, as you have described, and it's been known about for years, I would assume that scientists that understand this bond have come up with ways of cleaning these implants to weaken the bond so everything -- this entire polymer that you describe would go away.

Is that fair, that over the years people have come up with some sort of a cleaning protocol for that?

MR. HUTCHINSON: Object to form.

THE WITNESS: I didn't find one. But I did find some articles, and I referenced it in my report here, of Dr. Robert Guidoin. He wrote an article, and the main context of that article dealt with the difficulty in cleaning explants.

BY MR. MONSOUR:

Q. Okay.

A. And he talked about the fact that you need to be very careful because you'll have -- you probably would have to use harsh chemicals and so forth.

So that tells me -- and I think that was in the '80s, the late '80s -- that he, himself, had missed this rather simple chemistry and was not giving consideration to this bond.

Q. So you think Dr. -- is it pronounced "Gee-don"?

A. I'm really not sure.

Q. I've been saying "Gwe-doin" or whatever. But we know who we're talking about?

A. I think we're talking about the same gentleman.

Q. So I want to go back through your questions. Because when I look at your report, it seemed like you were citing Dr. Guidoin as an authority. Are you telling me you were not?

A. Well, I'm citing him to show that he, as an authority -- he's been mentioned in this litigation on several issues --

Q. Right.

A. -- and providing explants and so forth to Ethicon and so forth, and he, himself, is citing how difficult it is to remove this material and to clean -- let's put it this way -- to clean the explants.

Q. Okay.

A. And so my thought -- since I'm testifying and I don't ask questions, but my thought can be in the form of a question, why didn't he know this?

Q. Okay.

A. I mean, it's 1988. He knows there's a reaction going to on. He knows that the explants are covered. He says, "This stuff here is difficult to get off." And I'm thinking, "Why don't you go back to the fundamental chemistry of how it was put there in the first place?", i.e., the reaction of flesh when you drop it in formaldehyde to preserve it and to fix it.

Q. Where do you find that Dr. Guidoin is saying it's hard to get off and we don't know? Is it this?

A. Well, let me look at your article here.

Q. What I've highlighted is the first part of the quote that you have on page 16 and 17 of your report.

A. Yes, sir. Do you mind if I cite the title of this article?

Q. Absolutely.

A. The article is from a journal called "Biomaterials," Volume 17. It was written in 1996. The title is "Chemical and Morphological Analysis of

Explanted Polyurethane Vascular Prostheses."

Q. Here, let's do this. I've got a clean copy. I'm going to mark it, and I'll give you this one.

(EXHIBIT NO. 4 MARKED.)

BY MR. MONSOUR:

Q. Here is No. 4. I'll give you this one, and that's for you, and you give me that one back.

A. And continuing that, after the colon, it says, "The challenge of removing fixed adhering tissue."

Now, it's important. The challenge, meaning it's difficult of removing fixed, i.e., the fixation process -- I've talked about adhesion, adhering tissue.

Q. Now, the substances that he's talking about, in all fairness, he's not talking here about removing from polypropylene. I think he's talking about polyurethane.

Does that matter?

A. No, sir. Not if it's in flesh, it doesn't matter.

Q. So would the same thing happen to a polypropylene implant as a polyurethane implant?

A. When you say "the same thing," if a

polyurethane implant/explant were in the body and had flesh on it and had been preserved in formaldehyde, yes, sir. It doesn't matter what you're cleaning. If that object comes out and goes into formaldehyde, there's a fixation product that forms around it.

Q. So here's -- again, we're going to talk about -- this is me talking as a regular person. Your theories in this litigation as to the coating that's on the outside of the Prolene isn't so much dependent upon the Prolene. It's more dependent upon the flesh and the formaldehyde bonding; is that right?

A. Well, that's the two components that produce the encasement around the Prolene or polyurethanes or whatever.

Q. Right, right. But am I right? I mean, that's basically what you're saying.

Whether we make the implant polypropylene or polyurethane or poly-whatever, what you're talking about is the reaction that's going on on the outside that forms between the flesh and the formaldehyde?

A. On the surface of whatever you would have in flesh.

Q. And so if you can get that flesh-formaldehyde combination off, underneath you would have pristine material?

A. Yes, sir.

Q. Okay.

A. If you get it off without damaging the object that you're looking to evaluate and determine if it's --

Q. Okay. And you don't quote that, but that's the next thing that's listed in this article. If we look, your quote says -- and I'll read your quote for anybody that's reading this deposition that's not looking at it.

But your quote says, "In order to study the surface chemistry of explanted prosthesis, it is necessary to remove all the tissue that may have grown over and within the prosthetic structure," correct?

A. Yes, sir.

Q. "In the event that the explant has been treated with a fixative agent after retrieval, such as formaldehyde or glutaraldehyde, the tissue will be cross-linked. And the only effective way of completely removing it is to use hydrolytic chemicals," correct?

A. Correct.

Q. "Depending on the degree of cross-linking, strong chemicals and/or extreme hydrolysis conditions may be required," correct?

A. That's what it says, yes, sir.

Q. And then if we continue -- that's where your quote stops, but I want to read a little further because I think it's what you just told me.

"Under these circumstances, caution should be exercised when using such severe chemical conditions because of the risk of modifying the inherent chemical and physical structure of the biomaterial," correct?

A. Correct.

Q. And that's what I think, I think, you just told me was, we want to take the outer layer off, but we don't want to go so far as we damage the implant.

A. Absolutely.

Q. Okay. Good. We're on the same page. Sometimes I read stuff and I don't know that what I'm reading is what I think I'm reading, so I'm at least on the right page.

Now, here's one of the questions that I have. It says here, "In the event... The only

effective way of completely removing it is to use hydrolytic chemicals," right?

A. That's what he says, yes.

Q. Do you agree with that statement?

A. I do.

Q. So what is a hydrolytic chemical?

A. Water. Something to hydrolyze or break apart a chemical bond with water. That's one thing.

Q. Okay.

A. Acids could be in water, in aqueous solutions. But water, in my opinion, is the very best one to use, and that's what we used.

Now, contrary to what Dr. Guidoin commented, we didn't use dangerous chemicals. We didn't use chemicals that would affect the structure of the fiber. We used a very mild set of circumstances, i.e., water. It's not a strong acid. It's not a strong base. It's a hydrolytic chemical, but it's water.

Because of the reaction that I showed you, this reaction I'm pointing to on page 17, water is your hydrolytic chemical, and the reaction goes this way. Water reacts with the cross-linked methylene bridge, breaks it apart, goes back and gives you -- regenerates formaldehyde and the protein material

that's -- the protein.

Q. So this equation, this bond that forms as described on page 17 of your report, in your opinion, can be broken with hydrolytic chemicals?

A. No, that's not exactly the way I stated this.

Q. Okay. You just lost me then. I was doing so good.

A. I'm going to go back and redo this, redo my statement.

If you look at the equation on page 17, you see a protein that's going to react with -- and that's plus -- formaldehyde. And then you have an equilibrium arrow that says it produces protein-methylene bond bridge. It cross-links it. That's a fixation process. Then when that has happened, the proteins have been fixed.

Q. Okay.

A. And if you envision the fiber as being this glass of water, they are all around it, and it affixes it, holds it.

Q. I got you.

A. So now you have a coating of the fixation product around the Prolene fiber. All right. Now, that was formed when they took the explant from the

human body and put it in formaldehyde. They do that to preserve it.

Q. Right.

A. They also do it to fix it so that if some pathologist wants to slice a piece of it, it's rigid enough that it can be sliced and given a decent microtome sample.

Now, if somebody said, "Well, I want to remove that material," well, go back to basic chemistry, the chemical reaction here, and say, "Well, since this is an equilibrium reaction, if I add water to it and put the water into the cross-linked material" -- in our case, we added heat. We used 70 degrees. Now, why did we add heat? Because heat increases the rate of the chemical reaction, and I didn't want to sit around for a month waiting for this reaction to take place.

Q. Fair enough.

A. So we put that in water, and we heated it. And see what happens? It reverses.

Q. All right. So let me stop you there.

A. All right.

Q. So to break this bond, all I've got to do is stick the explant in water. And if I don't want to wait around a month, I heat it up a little bit?

A. Well, use the protocol that we have described in here, yes, sir. But that's basically -- generally speaking, that's correct.

Q. And this is where I'm kind of -- this is where I -- you know --

A. It's too simple, isn't it?

Q. That's kind of my question. So, basically, my guys are so dumb they don't know to just stick it in water. That's what you're saying?

MR. HUTCHINSON: Object to form.

BY MR. MONSOUR:

Q. I mean, that's pretty much what you're saying, right?

MR. HUTCHINSON: No. Object to form. He's not answering that, Counsel.

THE WITNESS: No, sir, I'm not saying that. I'm just saying this is what I do. This is the chemistry that I use. It's very well stated. It's 66 years old. And some other folks are missing that, and I don't know why. That's their issue. But I'm explaining what I've done, and what I've done is good science.

BY MR. MONSOUR:

Q. Let me do this. I'm going to ask my

question in a more gentlemanly manner, because my experts might end up reading this deposition. So I'll ask it in this way. I won't use the word "dumb."

If my experts had just known to stick these explants in water, they could have gotten off this cross-linked protein-formaldehyde polymer that formed on the outside of the explants and could have just looked at the pristine stuff?

MR. HUTCHINSON: Object to form. It also calls for speculation.

BY MR. MONSOUR:

Q. Right?

A. It's a little bit more -- not complicated, but there's a little bit more to it than just sticking it in water.

You have to put it in water. You need to heat it up. You have to be careful with the explant. But, basically, this chemical reaction will clean the explants.

Q. All right. Now, as I look at your -- as I look at your -- I think it was your cleaning protocol, the one that had all the colors on it, --

A. Yes, sir.

Q. -- you mentioned using bleach.

A. Yes, sir.
Q. Why do you use bleach?
A. Well, because when you reverse this reaction, you undo the cross-linked material, and you still have flesh.
Q. Okay.
A. A quick, easy, mild way of getting rid of that is to use a little bleach, and then it's gone.
Q. So let me see if I understand this. The water breaks the bonds. The bleach has a way of removing the broken-down remnants of what the bonds had formed?
A. Correct, the flesh.
Q. The flesh.
A. Uh-huh (affirmative response).
Q. But then there's also formaldehyde that's there too, and it gets rid of that as well?
A. Yes, sir.
Q. So, literally, if I want to clean these things, if I do water and bleach and do those well, can I clean these perfectly?
MR. HUTCHINSON: Object to form.
THE WITNESS: When you say "perfectly," I'm not sure that you will ever get 1,000 percent of all the proteins off, but

you'll have a very fine, pristine type material that you can examine.

BY MR. MONSOUR:

Q. Okay. So let me ask this question. And this is, again, one, two, three, four. Okay. You're talking to four (indicating himself).

Why when you say, I don't know that you could ever get all the protein off, if all you really need is some water to break it down and some bleach to get what's broken down away, why couldn't you get it all off?

A. Well, we found -- and you'll see as we look through these scanning electron micrographs that we've taken after -- even our -- not five steps, we'll see that if we look at some of our scanning electron micrographs, that after these five major steps of cleaning that we've done, there's still a little speck that you can see where there's remnants of protein that's still on the explant.

So when I talk about simply putting in -- if I have enough time that I can wait and put this in water, give some heat to it, it will clean the explants efficiently as any process as you can find. It's all in the chemistry right here.

Q. Okay.

A. This equation defines what can be done and what we did.

Q. Okay. Let me ask this: Do you believe that when it's implanted in the body, the Prolene is implanted in the body, that it can undergo oxidative degradation?

A. No, sir.

Q. And you're unequivocal about that? The Prolene, when it's implanted, does not degrade when it's put in the body, in your opinion, true?

A. That's true, sir.

Q. What would you need to see, what evidence would you need to see as a scientist to convince you that it did undergo degradation in the body?

A. There would need to be a carbonyl index or carbonyl bonds formed. There would need to be a significant reduction in molecular weight. There would need to be a significant reduction in physical properties, such as tensile strength and elongation.

And if you do not have those characteristics occurring as a result of implantation, then the product did not degrade, the product being Prolene.

Q. So what are some tests that you could do to test whether or not an explanted piece of Prolene

has degraded? In other words, you've mentioned carbonyl bonds, molecular weight, physical properties, tensile, all those kind of things.

A. (Witness nods head affirmatively.)

Q. What are some tests you could do to look at explanted Prolene to see if it was degraded?

A. Well, you would run the tests that I've just mentioned.

Q. Okay.

A. You would perform the activities, the scientific activities that I just mentioned to you, i.e., you would use a Fourier transform infrared spectrometer, FTIR, and you would get a fingerprint of the chemical composition of the surface of the explanted material. And if there was -- if there was hydrolytic bond breakage, as would occur -- or let's just stay bond breakage that would occur under the circumstances that you've asked, what I would need to show, it would show whether there were any bond breakages or not with strong carbonyl absorption.

Then, in addition to that, you would have explants that would have lost its physical strength. Its elongation would be less. Its tensile strength would be less. Its compliance would be less. So

those are the characteristics. Now, they all have to follow each other.

Q. Okay.

A. So molecular weight would be less.

Q. So it's talk about FTIR.

A. Okay.

Q. To show degraded polypropylene or oxidized polypropylene, where do you have to have a reading for on FTIR?

A. You'll get a carbonyl reading somewhere in the range of 1750 to 1730 in general. That's reciprocal centimeters.

Q. So if we look at an FTIR report and it shows a reading between 1730 and 1750, is that evidence of oxidated polypropylene?

A. Well, not necessarily in this case. It would say what you need to do is look a little farther at some of the other tests that we've talked about.

Because in Prolene you have two materials that also have carbonyl bonds, and that's calcium stearate and dilauryl thiodipropionate, DLTDP, which is an antioxidant.

Q. So the first one is called calcium what?

A. Stearate, S-T-E-A-R-A-T-E, --

Q. Okay.

A. -- and then your antioxidant, DLTDP, those both. So you've got to be careful. You may be seeing one of those.

Q. All right.

A. So what we would then need to do is say, "Okay. What about molecular weight? What happened to molecular weight? And then, after that, what happened to our physical properties? We need to do tensile and elongation and do that curve and see whether or not the toughness has been diminished."

Q. Okay. Hold on. So we're going to go through these one at a time. You moved quick. All right.

So the first thing we're going to look at, if we've got an FTIR and it has a positive reading at, let's say, 1742, in your mind, you're saying that could be oxidated or degraded polypropylene. Let's do some further tests, correct?

A. I think that's correct.

Q. And so the next thing you would do is you would test it for calcium stearate and DLTDP?

A. Well, because they have carbonyl groups and could show up in that range, that's why I would say let's do something else to rule them out as the

reason for the carbonyl group.

Q. Okay.

A. All right. Then you run molecular weight. And if there is degradation, there will be a decline in molecular weight. And after you've run molecular weight, you say, okay, that suggests to me we've got a problem here. We've got oxidation. Let's do our physical property tests to make sure that absolutely, 1,000 percent sure that we've got degradation.

Q. So let's look at some of these, and let's talk about them.

How do I test -- so we've done our FTIR. Let's say I've got a positive reading at 1742. So I go to step two. I look at calcium stearate. How do I look at that?

A. Well, in the spectra, if we get a spectra and there's a carbonyl group in the range we talked about, that may be calcium stearate. And we can't really tell 1,000 percent if that's calcium stearate, if it's DLTDP, or if it's a C=O formed from a ketone from the oxidation of Prolene. But we know there's a carbonyl group. We just don't know which of those three it might have come from.

Q. Can I determine which one of those three

it might have come from? Are we able to do that?

A. Not just from an infrared spectra. That's why you need the additional tests that I'm talking to you about.

Q. So what you're saying is --

A. Very indicative that there's an issue here that could suggest we've got oxidation, but we've got to refine these tests to make absolutely certain that there is oxidation.

Q. And, at that point in time, that's when you go look at molecular weight and physical properties?

A. Yes, sir.

Q. Okay. I think I got it. So you get a positive reading at 1742 on the FTIR, and at that point in time you know it could be one of three things: Oxidated polypropylene, calcium stearate, or DLTDP, correct?

A. Yes.

Q. Now, you can't really tell which one it is because it's only showing positive for a carbonyl group; therefore, you go to a second round of tests, which would include molecular weight and physical properties, correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: Yes.

BY MR. MONSOUR:

Q. Molecular weight, how do we measure that, and how significant does the molecular weight drop have to be for you to think it's significant?

A. You measure molecular weight by gel permeation chromatography, GPC as it's talked about, or it's also referred to as size exclusion chromatography. And that allows you to determine if there's been a significant decrease in molecular weight.

You will get a number-average molecular weight, you'll get a weight-average molecular weight. And the weight-average molecular weight and the Z-average molecular weight will tell you the higher molecular weight components.

If they've been -- if we've had a significant reduction in molecular weight, that affected the higher molecular weight components. If there is a significant reduction in molecular weight, you say, okay, we may have another issue here. Let's check it and make absolutely sure. Let's do physical property tests.

Q. So question, you just used the term "a significant drop in molecular weight." I'm not a

polymer guy. What would be a significant drop in molecular weight?

A. I would say 20 to 30 percent, maybe more. I would have to look at the numbers to see. Let's restate that. Let's use 30 percent as a significant drop.

If it's going to oxidize, it will give us that kind of reduction. There is some error in molecular weight determination, so we have to keep that in mind.

Q. And what is the error in molecular weight determination?

A. It depends on who does it, and it would be in the range of around 10 percent. So we have to --

Q. Are you saying the margin of error for molecular weight measurements is about 10 percent?

A. It can go as high as 10 percent, yes, sir.

Q. So one of the issues that we have with molecular weight measurements is if the margin of error is 10 percent either way, that could get you fairly close to your 30 percent that you're talking about, right?

A. I'm not sure. I don't understand.

Q. Sure. If the margin of error is 10 percent -- is it 10 percent total or 10 percent

either up or down?

A. Well, you could be estimating them. Let's say you had 330,000. 10 percent is 33,000. If you take that off, you're down around 30,000, so whatever that number would be. So it's plus or minus that number.

Q. Okay. Good. But that range, a 10 percent range in one direction combined is about a 20 percent swing from top to bottom. That's, I guess, what I'm getting at.

What you're telling me is once you get to about 30 percent, that's when you can really say that there's probably been a molecular weight loss. And I guess my point is 20 is not that far from 30. That's why you're going to the next test, which is physical properties and toughness, right?

MR. HUTCHINSON: Object to form.

THE WITNESS: That is correct.

BY MR. MONSOUR:

Q. Okay.

A. You want to make certain.

MR. HUTCHINSON: Doug, after you go through physical properties, can we take a little break?

MR. MONSOUR: Yeah, absolutely.

THE WITNESS: And one of the things I want to emphasize is all of these things have to happen.

BY MR. MONSOUR:

Q. You've got to do them all?

A. All have to happen.

Q. If I were to do just FTIR testing and say, ah-ha, you would say, I'm doing bad science?

A. You're doing incomplete science.

Q. Incomplete science. Okay.

So the physical property testing would include -- you would look at tensile strength?

A. Yes, sir.

Q. Elongation?

A. Yes, sir.

Q. What else?

A. That will give you a value for toughness. If you plot tensile strength and elongation, that will give you a value of toughness, and you do that against a control. Of course, you always have to use a control that hadn't been subjected to any of the tests that we're saying we're performing here.

Q. Okay.

A. No control, your data is of no significance.

Q. So I'm going to write over here on the left-hand side "must have a control." Okay?

A. (Witness nods head affirmatively.)

Q. Is that a fair statement?

A. Yes, sir, it is.

Q. So how do you measure tensile strength, and how do you measure elongation?

A. Well, you use a machine called an MTS, a material testing system. There's an ASTM test for this. It requires at least five samples, five duplicate samples. In the case we're talking about, you would take fibers, Prolene fibers. You would clamp them into two clamps.

And this machine that we're talking about has the ability then -- we program it to move those clamps apart at a certain rate. You do that, and it stretches it and stretches it. And then it plots it on the recorder over here the amount of force that's being applied. And you're also looking at, well, how long had it -- from the original sample length of, say, like one inch, it goes two inches when it finally broke. That's 100 percent elongation. You can determine that.

So you're getting elongation and the strength required to break the fiber. When the

fiber is broken, that's its ultimate tensile strength. And that's also its ultimate elongation.

You plot that data, and that's how -- and the area under the curve, as I've shown you here in this report that I've written, is toughness.

Q. Okay.

A. And then you compare that to the control, the data that you've achieved.

Q. So give me -- tell me what you just told me and use fishing line as an example.

A. Well, you could put fishing line between the two clamps. You could put textiles between the two clamps. You could put leather between the two clamps. You can actually put concrete between the two clamps.

Q. And the heavier gauge fishing line would have different tensile strengths as the lower weight fishing line, correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: You're talking about the smaller braided line?

BY MR. MONSOUR:

Q. Yeah.

A. Because you measure it on area, yes, sir.

Q. Does that testing that you're talking

about, does that test both tensile and elongation?

A. Yes, sir.

Q. And do you test it all the way up until it snaps?

A. Yes, sir.

Q. And what's the snapping point called?

A. The ultimate tensile strength or the ultimate elongation. That's the snapping point, and finally it breaks.

Q. And what's it called again?

A. Ultimate tensile strength.

Q. Okay.

MS. KROTTINGER: Can we take a break? Technical difficulties.

MR. MONSOUR: We are going to take a break.

(A BREAK WAS TAKEN.)

BY MR. MONSOUR:

Q. We've taken a short break, Dr. Thames. Are you ready to continue?

A. Yes, sir.

Q. We were kind of talking about some of the process that you would go through after you would get an FTIR reading that was positive for -- or potentially positive for degraded polypropylene,

correct?

A. Yes, sir.

Q. And we had gotten down, and we had talked about how you had first tested and that it came in that range of 1730 to 1750. That would start your inquiry, and you would then follow up with molecular weight and physical properties and those kind of things, correct?

A. Yes, sir.

Q. Now, you said that you thought a 30 percent drop in molecular weight would be kind of where you would -- that's where you would determine something was significant?

A. Well, first of all, you've got to take into consideration the -- who's running the test and what kind of error we think. Beyond that, if we've got anywhere from a 20 to 30 percent reduction in molecular weight, I would be concerned, and then we would go to the next test.

Q. Okay. Now, where did you -- you know, one of the things we do when we've got litigation -- and you know this because you prepared your report. We ask a question. We say, "What's your opinion?" And then we try to find out is there anybody else that agrees with you.

So when you're talking about a 20 to 30 percent drop in molecular weight, is there an authority that you would rely upon for that drop as being significant?

A. I haven't pursued that, no, sir.

Q. So would it be fair to say that the 20 to 30 percent drop in molecular weight would be the Shelby Thames' criteria, and you are not certain if there is any support in the literature for that?

MR. HUTCHINSON: Object to form.

THE WITNESS: I haven't really looked for it. But what I also want to be sure we include is that all of the steps that I've talked to you about have to be performed in order to come to a final conclusion.

BY MR. MONSOUR:

Q. Right, right. But I was just asking about that one specific area, the molecular weight.

A. Yes, sir.

Q. There might be a bible on this stuff that I don't even know the name of. So if there is a -- you might say, "Yeah, it's in Bill's Bible of Polymer Chemistry, you dummy." I don't know that that book exists.

So my question would be, is there any

authority that you would cite for that being the drop?

A. I think I've answered that.

Q. Okay. Now, as far as your -- you mentioned when you were going to do the physical properties test you would follow the ASTM guidelines?

A. Yes, sir.

Q. Why would you follow ASTM guidelines?

A. Because those are guidelines that have been set by people in the profession to say, well, we've got to consider these approaches and do it this way. Otherwise, the data we get may not be reliable.

For instance, they require five specimens be run and take the average of that. When you're running a test, like an MTS test, tensile strength and elongation, in the process of putting the material in the clamps and clamping them down, number one, you could not have your clamps set just right. And so the number you got there -- the clamp could slip, and so the elongation would be greater than it actually is.

So you want to make certain that you have enough samples replicated that if those things occur

and you have one that is completely off the charts, you throw that out and say that's an outlier. That data is not really true. So that's why you run five samples and make sure that the number you are seeing is a significant number.

Q. If there are not five samples run, would you place much credibility into the results?

A. I would give -- the credibility I would give to it would determine how many samples were run. The fewer the number of samples, then the more questionable that becomes.

Q. Okay. You've used the word "toughness"?

A. Yes, sir.

Q. What does "toughness" mean?

A. Well, I often use a downhome example of toughness. You may not remember this because you may not be old enough. But there used to be a gentleman by the name of John Cameron Swayze who was on TV, and he advertised Timex watches. He would do some awful things to a Timex watch. He would put them on a propeller of an outboard motor and crank the thing and show it on TV. And he said, "It takes a licking and keeps on ticking."

Q. I actually do remember that, I think.

A. That's tough.

Q. So toughness is kind of what it sounds?
A. Yes, sir.
Q. So it's the ability to, I guess, be hit or be challenged in some way physically and not fall apart?
A. And still perform.
Q. And still perform. Okay.
You said to get to toughness you use the tensile and elongation measurements?
A. Yes, sir. You plot those. It's like I've shown in my report here.
Q. Now, one of the theories that has been proposed is that your cleaning procedure might be a little too much.
Have you ever heard that?
MR. HUTCHINSON: Object to form.
THE WITNESS: I don't believe in this cleaning procedure I've heard that, but, you know.
BY MR. MONSOUR:
Q. Well, let me ask you this: Is it possible in your cleaning procedure that you've done that there is oxidized polypropylene on the surface of the explants, and because your polypropylene -- because your cleaning procedure is so thorough, you

actually clean the layer of degraded polypropylene off the surface?

A. I don't believe that happened, sir. That's why we used this very mild set of circumstances.

Q. Okay.

A. I mean, when we put this in water, then the reaction reverses. And then we used sodium hypochlorite to take care of the flesh, to move it out of the way. That's an oxidizing environment. So we're not going to remove something that's oxidized with an oxidizing environment.

Q. Okay.

A. So this is a very mild set of circumstances. I don't believe that's true.

Q. Your cleaning procedure actually involves a few more things than just water, heat and bleach, --

A. Yes.

Q. -- in all fairness, doesn't it?

A. Yes, sir. We use protein to -- which in the event there's still clean protein, it will help remove some of it. It's an enzyme called Proteinase K, P-R-O-T-E-I-N-A-S-E-K, I believe.

Q. So you used some Proteinase K?

A. Yes, sir. It's an enzyme.

Q. And what does that do?

A. Well, it helps open the proteins and the flesh more so that if there's any carbonyl groups that are there that haven't been removed, they're taken away. It's just another cleaning process basically, a little bit more rigorous. But it's an enzyme. It's a mild enzyme, but it works a different way.

Q. Is there any way that you can guarantee that you're not cleaning off a layer of oxidized polypropylene? Can you be 100 percent sure that you're not doing that?

A. I feel I'm 100 percent sure I'm not doing it because I'm using these mild conditions.

In the article that we talked about here with Guidoin, he talks about strong chemicals. We're not using strong chemicals. To me, this is as mild a set of circumstances that you could get to clean these explants.

We're using the reversal of a basic chemistry that formed the casing or the fixation process. We're just reversing that.

Q. Don't you use some steps in your protocol that have some like vibration or something in there?

A. Sure.
Q. What's that?
A. That's in case you've got a piece of loose material that doesn't come off, you help that by vibrating it.
Q. So, basically, you're cleaning -- and some of your cleaning steps kind of involve repetition. You kind of do things more than once, right?
A. That's correct.
Q. So your cleaning steps involve water, bleach --
A. Well, let's look at the --
Q. Here it is right here.
MS. KROTTINGER: It's on page 100.
BY MR. MONSOUR:
Q. Oh, there was another question that I was going to ask you. I do want to clear this up before we go further so that we're not confused.
I got from Mr. Hutchinson new cleaning steps two days ago that are different than -- I don't know whether they're different from this or they're different from the original report.
MR. HUTCHINSON: Why don't you ask him why he amended -- he served amended case-specific reports?

BY MR. MONSOUR:

Q. Would you tell me why two days ago we got amended case-specific reports with different cleaning steps?

A. Because one of the protocols that we have used was inadvertently placed in the case-specific reports. And in those cases, we were using longer hours to clean the explant. And in the case-specific reports, as you know, we have a lot of explants to clean. They're coming in on a regular basis. We needed to find a way to do it in a shorter period of time.

So we reduced the period of time from the original cleaning explant. So the ones in the case-specific report were being cleaned in shorter periods of time, but the process was the same.

Q. So you served 20 case-specific reports. In each of those case-specific reports, the first 20 that you served, the cleaning protocol that you had in there was a protocol that was actually not followed. Is that true?

A. That's correct.

Q. And then two days ago, you amended and realized, oh, shoot, I gave them the wrong one. I actually used this second one, correct?

A. Yes, sir.
Q. Is the second one that you amended in each of the 20 reports identical to what is on page 100 of your report?
A. No. This is not the amended one.
Q. So 100 is not the amended one. 100 is the incorrect one?
A. Well, it's a different one. I wouldn't call it incorrect. It's a different one. It's the same steps, but they're at different -- for different time periods basically.
Q. But it is the incorrect one?
A. It's in the wrong place.
Q. Which would make it incorrect.
MR. HUTCHINSON: I think it's outdated. It's outdated protocol.
MR. MONSOUR: Time-out.
(OFF-THE-RECORD DISCUSSION.)
MR. MONSOUR: So let's go back on the record. You ready?
THE WITNESS: Yes, sir.
BY MR. MONSOUR:
Q. So one of the questions that I have is, if I'm looking at your protocol on page 100, that is not the protocol that you followed with the explants

that you did, correct?

A. Yes, sir.

Q. You changed them, as you're saying, to shorten the time because you had a lot more to do?

A. Yes, sir.

Q. Were you still able to achieve good results with the shortened time frames?

A. Yes, sir.

MR. MONSOUR: Do we have one that's the newer ones -- actually, hold on. I bet I do right here. I think this is an amended one. Okay. I've got it right here.

BY MR. MONSOUR:

Q. So how did you catch the error that the wrong one -- that the wrong cleaning protocol was included in the general and the case-specific reports?

MR. HUTCHINSON: Object to form.

THE WITNESS: In looking at the cleaning protocol, I noticed that this was 42 hours rather than the short -- with the original cleaning schedule. You'll see on the third step of the original that it says 70 degrees Centigrade for 42 hours and then spray rinse.

I noticed that this was 42 hours, and it

should have been about half that. And then I went back and looked and found out that we had put the wrong cleaning schedule in the case-specific reports.

BY MR. MONSOUR:

Q. So, in all fairness, you got the wrong cleaning schedule in 21 different reports?

A. That's correct, initially.

Q. But it is accurate?

A. That is correct.

Q. Are you sure it's accurate now?

A. Yes, sir.

Q. So let's go through -- well, let me ask you. Should we go through the wrong procedure, or should we go through the right procedure?

MR. HUTCHINSON: Object to form. For the objection, it's not the wrong procedure. It's an outdated procedure, Counsel.

THE WITNESS: That was the point I was trying to make. The procedure is not wrong. It's outdated. It wasn't the one we used. Now, the procedure we used is the shorter one, the shorter time frame. So we probably should use that because that's in 21 case-specific reports.

BY MR. MONSOUR:

Q. So let's use the one that you actually used. Let's use that one.

MR. MONSOUR: Do you have a clean copy of one of those?

MS. KROTTINGER: I do.

MR. HUTCHINSON: Of the case-specific report?

MS. KROTTINGER: We'll just use Justus.

MR. MONSOUR: I just want to look at --

MR. HUTCHINSON: Not with me, but I'll go get one.

MR. MONSOUR: Here, this is from Justus.

BY MR. MONSOUR:

Q. So I'm going to hand you your amended case-specific report from Justus, J-U-S-T-U-S.

MR. MONSOUR: We'll mark it as Exhibit 5.

(EXHIBIT NO. 5 MARKED.)

BY MR. MONSOUR:

Q. And this is not -- I'm using this as an exemplar, not as my case-specific depo for Justus. But this is just the one that I have handy. We'll talk about the Justus case specifically in the Justus case deposition. Okay?

A. Yes, sir.

Q. So if we look at this, if we look at the steps that were taken, can you kind of walk us through -- well, first off, in Exhibit 5 in front of you is a cleaning protocol, correct?

A. Correct.

Q. That is the correct cleaning protocol that you actually used to clean the 20 different explants that you cleaned and looked at for case-specific reports, correct?

A. That's correct, sir.

Q. This protocol that is set up here, where did you get this protocol from?

A. I devised the protocol in discussing this issue with Dr. David Ong -- Kevin Ong -- excuse me -- from Exponent. And I need to make it clear that he is actually the one that did the cleaning of the materials.

Q. Okay.

A. I put it together in discussion with him based on the chemistry that we talked about, the reversible reaction and the mildness of that, and that's how this was brought about.

Q. So a couple of questions. I want to go through this. I'm not an expert in cleaning things,

as we've discussed.

As far as the protocol, you came up with it with Kevin Ong?

A. Yes, sir.

Q. Was it more you coming up with it or more Mr. Ong coming up with it?

A. More my coming up with it. "This is what I would like for you to do. Are you okay with that? Do you have any reason to believe this is not what we should be doing?", those kind of questions.

Q. I don't know who Kevin Ong is.

A. He has a Ph.D. in biomaterials, and he works for the Exponent company.

Q. What is Exponent?

A. It's a commercial laboratory providing scientific services to the scientific community. It's very broad.

Q. Did you select Exponent?

A. No.

Q. Did Ethicon select Exponent?

A. I'm not sure. My attorneys were involved with Exponent. I'm not sure who selected it.

Q. Had you ever worked with Exponent before?

A. Yes.

Q. In what capacity?

A. I just went to their labs a couple of times on other cases where I would pick up samples or see what they had done, nothing to do with this case.

Q. In litigation matters you've worked with them?

A. Yes, sir.

Q. Where are they located?

A. I don't know. Philadelphia is one place. But they're out in California, and they've got other places, which I don't know the details of.

Q. As far as the protocol, when I first asked you where it came from, you came up and actually pointed at your head. Is there any -- is this protocol, this cleaning protocol for explanted implants, is this protocol published anywhere or peer reviewed anywhere?

A. Not to my knowledge at this point.

Q. Have you ever seen this specific protocol used before?

A. Not to my knowledge.

Q. Is this protocol -- are you familiar with the ISO standard for cleaning explants?

A. It's my understanding there isn't really a specific ISO standard for cleaning explants, but I

didn't really look.

I understand the chemistry of the formation of the proteins around the fibers, and I wanted to devise a technique that was as mild as possible, and I've done that, and that's what we've used to clean these explants with.

The other thing that is important that you haven't gotten to yet, but I need to say it at this time, is after each of these steps, after each of the cleaning steps, the explants were sent from Dr. Ong back to my laboratories where we performed FTIR, scanning electron microscopy and light microscopy on them at each step so we could see the progress of cleaning. And that information is included, of course, in each of these case-specific reports.

So what we were doing, we were following them. We basically could see with our instrumentation if that process was being effective or not.

Q. So what you're saying is -- and Dr. Ong is O-N-G?

A. Yes, sir.

Q. Dr. Ong is -- where is he located? Philadelphia?

A. That's right.

Q. So he would do one of these steps and then ship the implants back to Mississippi, and you would do the FTIR and light microscopy, send them back to him, and he would do another step and send it back to you, and you would do more FTIR, light microscopy, and send them back the whole way through?

A. That's correct.

Q. So give me an example. How long did the whole process take? Like when you got an explant, from the time you got it until you completed the steps, is it a few-week process?

A. I can't really tell you. I would have to go through here and look at the time frame that they kept the explant and then add a couple of days for transmitting them back and forth. Whatever that works out would be the time.

Q. Y'all just overnight them back and forth?

A. Absolutely.

Q. Okay. Now, a couple of the steps I wanted to ask you about.

A. Sure.

Q. Did you use a control; in other words, did you send a control through this process?

A. Absolutely. You must have a control.
Q. You know how I know that?
A. I said it before.
Q. Because you told me. See, I wrote it right there, "Must have a control." I'm a good student.
A. Yes, sir. I like that.
Q. Must have a control.
A. You'll pass my test when this is over with.
Q. I tell you what, I think I might. I might.
So as we look through here, some of the things that are happening are we go through the first step, distilled water, correct?
A. Yes, sir.
Q. For one hour?
A. No, sir, 30 hours. It's 70 degrees -- oh, you're talking about step one?
Q. Yeah, I said first step. I'm sorry.
A. No, it was my mistake. They soaked it in distilled water for one hour, yes, sir.
Q. And then it goes -- the second step is ambient overnight drying followed by SEM.
A. They performed an SEM. It's in their

records, and those documents will be presented by Dr. Ong. He's also presented those to me. You have those, I believe.

MS. KROTTINGER: Uh-huh (affirmative response).

MR. MONSOUR: Just as an aside, is there a deposition set up for Dr. Ong?

MR. HUTCHINSON: No.

MR. MONSOUR: Is he a testifying expert or a consulting expert?

MR. HUTCHINSON: I don't know which litigation. Are you talking about the Wave 1?

MR. MONSOUR: Yeah.

MR. HUTCHINSON: He is a consulting expert, I think. He's not -- I'll tell you this, he's not a testifying expert.

MR. MONSOUR: All right.

BY MR. MONSOUR:

Q. So the second step is ambient overnight drying followed by SEM. What does that mean?

A. Ambient drying is drying at room temperature. And then after it dried at room temperature -- you see it had been soaked in water for one hour, dried at room temperature, and then

they performed SEM analysis, and then they sent it me.

Q. Was the first step primarily to basically just get -- wash off as lightly as you can, let it dry, and then take pictures to kind of know what your starting point is?

A. That's exactly right.

Q. Your second step, it says distilled water bath 70 degrees Celsius 30 hours.

A. That started my chemical reaction we talked about here.

Q. And 70 degrees Celsius is what Fahrenheit?

A. It's about 130, approximately.

Q. So that goes on for 30 hours. That's the start of your chemical reaction that we've talked about quite a bit, correct?

A. Yes, sir.

Q. And then the next step is what?

A. Sodium hypochlorite for 15 minutes. Because if we've gotten some -- we've reversed that reaction some, and we have some now free, unreacted tissue, and we want to get rid of it so that we're closer -- we're working from the outside moving in.

Q. Is it kind of like you're taking off layers? Is that a fair way to say it?

You put some water in. That breaks down the outer later, and then you take the bleach to get what you broke down, and then you go back in water and it breaks it down a little more. Is that a --

A. I think that's a fair way to look at it.

Q. All right. So NaOCl, is there another name for that?

A. Sodium hypochlorite.

Q. Is there another name for it?

A. Bleach.

Q. There you go. Like Clorox?

A. Yes.

Q. Do y'all actually use Clorox?

A. No. It's stated what we used here.

Q. So then the next step is after 15 minutes. The fifth step is what?

A. The fifth step is putting it in distilled water and letting it soak a while, one hour, and then you rinse it. That's the rinse where you clean it for one hour in distilled water.

Q. Okay. And, basically, when you're doing that rinse, you're trying to get off whatever tissue was probably broken down and removed by the bleach?

A. That's correct.

Q. Then the sixth step, would you explain

that to me?

A. That's a drying step. After five, we dry it, and then they take an SEM, and then they send that to me. Then we do our light microscopy, SEM, and we do our work.

Now, one thing I want to note here is, you see in blue -- what you'll see when you look at my work is you'll see before cleaning, after cleaning one, after cleaning two, three and four. That's how you'll see that in my report.

Q. And that's how you tie it in. So this is that step.

So if you take a picture after and it says "after cleaning one," it's after that step that you're talking about?

A. That is correct.

Q. Now, I do want to ask you this: SEM, what does that mean?

A. Scanning electron microscopy.

Q. And that would be -- let's use the Justus amended report again. Show me the SEM photos in here. Ah, here it is on page 13.

A. Yes, sir.

Q. So, as you just explained to us, the first cleaning where you're just kind of rinsing it,

you're putting it in a little bit of water to get most of whatever could be on there, you dry it out, and you take SEM. That's picture A in the --

A. That's correct.

Q. -- top left-hand corner.

A. That's correct.

Q. It goes through a few more steps. It gets through the sixth step, and then another photo is taken, and that's picture B.

A. Well, that's after cleaning one.

Q. Right. So that's after the sixth step, which is after cleaning one, which you have marked in blue on your cleaning protocol, correct?

A. That's correct.

Q. And then it follows all the way down through cleaning five, which is the 25th step, which is the picture that says Justus 1.1 SEM three after cleaning five, correct?

A. Yes, sir.

Q. Now, I do have a question for you. Some of these say SEM 07, SEM 05, 05, 02, 02, 03. What does the 05, 07, 05 mean?

A. We took more SEMs than I could include in this report. That's available for you. We just selected ones that we thought told the best picture

to explain what I want to talk to you about as we go through this.

Q. And so how many SEMs would you take of each one?

A. It varied.

Q. But when it says "SEM 5," you just numbered that picture 5?

A. Yes, sir.

Q. So there's probably a picture 4 I could look at, --

A. Sure.

Q. -- a picture 6 I could look at for that same level?

A. Yes, sir. It would depend.

Q. Okay. So hint to somebody getting ready for trial. If they wanted to, they might want to look at those pictures and see what they said, right?

A. Yes, sir.

MR. MONSOUR: That's my note to all the lawyers that are reading this three months from now. If you want to look at some pictures, they are available. Don't say I didn't tell you.

MR. HUTCHINSON: For the record, those

have been produced already.

MR. MONSOUR: Okay. Good.

MR. BOWMAN: Those are the ones produced yesterday?

MS. KROTTINGER: Well, two days ago.

MR. HUTCHINSON: Two days ago.

BY MR. MONSOUR:

Q. Let's go back to our cleaning protocol. The seventh step looks like distilled water bath, 70 degrees Celsius, 17-and-a-half hours, correct?

A. Yes, sir.

Q. Why this time did you do it 17-and-a-half hours instead of 30 like you did in the third step?

A. Well, number one, we needed to reduce the time because of the number of implants that we were getting in here. So we looked at these and said, well, this is doing a pretty good job. Let's reduce the time.

And, obviously, had we gotten through these five steps and they hadn't been clean, we would have to revise and go back and do a longer period of time. But it was giving us what we needed. We were seeing a reduction in the layer, the formation layer around the explant.

Q. Fair enough.

As in litigation, you had a deadline that you needed to meet. Sometimes you needed to cut a little bit here, but you still wanted to get it done adequately?

A. Accurately and adequately, yes, sir.

Q. The eighth step, what does it say?

A. Hypochlorite in the shaker for one hour.

Q. Now, if I look -- if I'm careful at looking at this, it looks like your NaOCl, your bleach, is different than the bleach you used in the fourth step?

A. It's the same.

Q. So could you tell me why does one say 10 to 15 percent NaOCl and the other one says 6 to 14 percent NaOCl?

A. Let me say this. Dr. Ong did this, and he may have had a different container of sodium hypochlorite, so I may be talking out of -- it may be 6 to 14, but it really doesn't make any difference. It's bleach.

Q. And then it says, "shaker one hour"?

A. Yes, sir.

Q. What's a "shaker"?

A. You put the sample in the shaker. And it's just that, it shakes the material back and

forth.

Q. And so --

A. That's to provide physical movement for if there's any hanging-on material that's been --

Q. It gets it off?

A. Yeah. It may be intertwined, and you're trying to shake that off.

Q. So the only thing that's in the shaker is going to be the implant, the bleach, and it goes in there and shakes back and forth for an hour?

A. That's correct.

Q. Then you take it out, and it says the ninth step is what?

A. 6 to 14 percent sodium hypochlorite, and it's in an ultrasonic bath for an hour.

Q. What's an "ultrasonic bath"?

A. It's a bath that's operated by ultrasonic waves. It's more vigorous than step eight.

Q. So how does it do -- how does the ultrasonic bath work? Assume for me the hypothetical that I might not work with ultrasonic baths that often.

A. Well, the way that I know to tell you that it works is that it's energy imposed on water such that it has the water waves moving very rapidly.

Q. All right. Then the next step is? The tenth step is what?

A. That's distilled water again and ultrasonic bath for one hour, but that's just distilled water.

Q. Is that basically to rinse the bleach off and any of the other flesh that has broken down?

A. Yes, sir.

Q. The 11th step is what?

A. Desiccation, drying. It's putting it in a desiccator. It's a glass vessel, and they pull a vacuum on it to hurry it up.

Q. And they only do that for one hour?

A. Yes, sir.

Q. And then you again look at it by SEM?

A. Yes, sir. And that's my after cleaning two.

Q. The 12th step is what?

A. They look at by SEM and send it to me.

Q. They send it to you after cleaning two.

And after cleaning two, you again will perform FTIR and light microscopy?

A. And SEM.

Q. But doesn't -- does Ong do the SEM, or you're doing the SEM?

A. He does it, and we do it.

Q. Okay. So y'all both do it.

Why is Ong doing SEM if you're doing it?

A. I think he wants to see the progression so he can tell how the cleaning process is moving along, and he wants to see that himself, which I understand.

Q. Is that a way for him to check that the cleaning is doing what it's supposed to be doing?

A. Yes, sir.

Q. So then y'all look at it. You do the SEM, the FTIR, the light microscopy following the 11th step.

You go to the 12th step, which is?

A. Distilled water bath, 70 degrees for 18 hours.

Q. So it's about the same as the seventh step, except it's half an hour longer, correct?

A. Yes, sir.

Q. And then you follow that up with the 13th step, which is?

A. Again, sodium hypochlorite in the shaker for four hours and then ultrasonic for two.

Q. Okay. So it's almost a combination of steps eight and nine?

A. Correct.

Q. And is there a reason why the 13th step basically listed as one and then eight and nine are listed as two?

A. I'm not sure I understand.

Q. Well, the 13th step has a shaker and ultrasonic bath.

A. Yes, sir.

Q. The eighth step is a shaker, and then the ninth step is an ultrasonic bath.

So you have it broken down there, and then on one of them you have it combined. I was wondering if there's any significance to that?

A. No, sir.

Q. The 14th step is what?

A. Distilled water rinse, and it's in an ultrasonic bath for one hour, and it's rinsed again. So they took the material out of the 13th step, put it in clean water, clean distilled water, and shook it again for one hour in the ultrasonic bath.

Q. Basically to get all the bleach and all the stuff that the bleach took off --

A. Yes, sir.

Q. -- off the implant?

A. Yes, sir.

Q. Okay. Then you go to the 15th step, which is, again, desiccation/drying for one hour, which is that vacuum drying?

A. Yes, sir.

Q. Again, there is SEM, FTIR, light microscopy, correct?

A. At my lab, yes, sir.

Q. And then there's the 16th step, which is a repeat of the 12th step, correct?

A. Okay. Let's see. Yes.

Q. And then there's the 17th step, which this is a new one. This is something that you haven't done before. What is it?

A. It's using Proteinase K, an enzyme to help break apart proteins.

Q. Okay. Now, why would you use the Proteinase K at this stage in the 17th step? How did you select that?

A. Well, if you think of the logic here, you start off with flesh and fiber, and we're working our way toward the surface of the explant. And when we will kind of get to the surface of the explant, that's where we find the strongly-adhered proteins that I talked to you about. They are saying to themselves, "I like it here. I don't want to go

anywhere."

So we use Proteinase K as a means to -- it's an enzyme, which is a little different cleaning mechanism to try to attempt to get rid of the last vestiges of proteins on the surface of the explant.

Q. This is going to sound stupid, but I'm going to ask it anyway. Is the bond, where things bond together, is the bond strongest where the bond is actually together versus kind of back away from the bond?

A. Well, you're asking a very good question. You're asking me the difference between a cohesive bond and an adhesive bond.

Q. Okay.

A. The cohesive bond is the formation of the bond between the proteins themselves, and that's part of what we're having to break apart.

The adhesive bond is the bond between the proteins and the fiber. We're attempting to break both of those.

Q. All right. So these bonds that are the hardest to break are the cohesive bonds?

A. Well, not necessarily. I have not measured that. In order to give you an exact scientific measurement, I would have to do a

measurement. But they are very strong. Both of them are strong.

Q. Okay.

A. And I have to get through that cohesive bond to get to the surface of the fiber with my Proteinase K before I finally can wash the last vestiges off.

Q. Okay. So is it a fair statement to say that Proteinase K is a stronger -- I'm at a loss for my words -- cleaner than bleach would be?

A. I don't think it -- that's a different one.

Q. It's different?

A. It's different.

Q. It might do some things that the bleach didn't do?

A. Yes, sir.

Q. So, now, if we go the 17th step, that's the Proteinase K followed by a water bath, and then the 18th step is more Proteinase K with an ultrasonic bath?

A. Right.

Q. Why did you do that?

A. Well, because we wanted to follow it with 17. You take it out, and you put it back into a new

bath, which is not contaminated now from anything that might have come off from the 17th step. Now it's in a new bath to finally do the same thing.

Q. Okay. Then we go back to the 19th step, which is what?

A. Distilled water and an ultrasonic bath for a one-hour rinse, and then they desiccated it in the 20th step and one hour drying, and they sent it to me.

Q. Okay.

A. If you'll notice the last steps before we come to the send to me, they try to clean it and get whatever residue might have been on there off of it and then dry it.

Q. So you can get a good picture?

A. That is correct.

Q. They know before they send it to you that you're going to be doing light microscopy, FTIR, and they want you to have as good as a sample as possible to look at?

A. That's correct.

Q. And FTIR, doesn't that look at the surface?

A. Yes, sir.

Q. So if there's a bunch of gunk on the

surface, FTIR might not be as reliable as you would want it?

A. Well, we do transmission, which means it goes through the sample that we're looking at. But if you have a lot of, as you put it, gunk on the surface, it's not what you really want to look at. Then that's what you're going to get a big picture of, and it's going to obscure other things that you really want to see.

Q. Right. So the 21st step is more distilled -- another long distilled water bath of eight hours?

A. Correct.

Q. Are you able to do a little less time now because you've cleaned off so much of it?

A. Yes, sir.

Q. And then the 22nd step is more bleach in a shaker for 18 hours?

A. Yes, sir.

Q. Now, one thing, it seems like -- is this your longest shaker with bleach?

A. I'll have to look.

Q. It looks like -- usually your longer times are more with -- well, there's one with Proteinase K. Usually the longer ones seem to be

with water.

Is there any reason why at this step you're going with more bleach in the shaker for a longer period of time?

A. Well, we've used Proteinase K. It has worked a different method and opened up some of the proteins, denatured them, and then we want to come in there and make sure we get those off. So that's why we use the shaker, because now we're getting down to the real tough guys that are adhered strongly to the surface.

Q. Now, it says the 23rd step is more bleach and an ultrasonic bath for two hours, correct?

A. Yes, sir.

Q. And then your final -- or the 24th step is distilled water rinse, ultrasonic bath, one hour and then rinse again?

A. That's correct.

Q. And that's pretty much the final cleaning. And then it goes to dry, and then you look at it and you take your final pictures?

A. Yes, sir.

Q. Now, the bonds that are formed between this cross-linked formalin and protein, where it is adhering to the surface of the polypropylene, is

that a strong bond?

A. Yes, sir.

Q. Is it the type of bond where if somehow they were still bound together and the protein was removed, could it pull some of the polypropylene with it?

A. That's possible.

Q. If the -- if -- and this is a hypothetical. I know you disagree with this. If the polypropylene on the surface was degraded, would it be easier to pull off with this strong bond that had been formed with the protein and the formaldehyde?

A. At that particular site, that might be the case. It's possible.

Now, you have to remember, by the time we get to here, we've basically cleaned the sample, and we've taken FTIRs and SEMs and light microscopy of these samples all the way. So we can follow what's happening. And it's not like we would have missed anything on the surface of that explant if it were there because what you just described happened.

That's why we've done all of these tests at every step of the way. We plotted them all: One, two, three, four, five. And in these reports,

you have FTIRs. After each of these steps, you have light microscopy after them, and you have SEMs after each of the steps.

Q. Let me -- I'm going to do a drawing here.

(EXHIBIT NO. 6 MARKED.)

BY MR. MONSOUR:

Q. Now, I'm about as good of an artist as I am a polymer chemist. Okay?

A. Okay.

Q. So I'm going to draw a cross-section of a Prolene fiber. This is my cross-section of a Prolene fiber. Okay?

A. Got you.

Q. If there was an outer later on the surface that was degraded, oxidized polypropylene, and if it was removed in the process, if that happened, it would, in theory, give the polypropylene implant a smaller diameter if that took place, correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: If you take some of the polypropylene off of the exterior surface, it will reduce the diameter by the amount that you took off.

BY MR. MONSOUR:

Q. And so I'm going to say "before," and then

I'm going to say "after." And I'm going to write at the top "hypothetical," because I know you disagree with this, "hypothetical."

So you see my diagram, which is, in theory -- here, I'll call it "cross-section of Prolene fiber."

Do you see my drawing?

A. I do.

Q. And you see before would be the outer, the diameter, and then after would be if that outer layer was removed where it would end up being.

Do you understand my basic premise of the question?

A. I understand your hypothetical.

Q. Okay. Here's my question. If that was taking place, is there a way to measure a fiber to say, well, they all started off at this measurement, and then when we were done cleaning, they had this measurement?

MR. HUTCHINSON: Object to form.

THE WITNESS: Well, I don't know if you've seen any of these fibers or not in the SEMs in the pictures and looked at them carefully.

BY MR. MONSOUR:

Q. I looked at the pictures, but I probably don't know what I'm looking at.

A. Well, you'll notice that when they're wrapped together, when they're knitted, there are sections that are linear in nature. And then as they begin to go into a knot or where they turn, the diameter changes.

So if you try to measure diameter -- and we've done this before. We've measured diameter. And you're talking about 3 mills out of 170-some-odd. So that's not a good way to try to make a determination on what you're trying to do.

What we've done to try to make certain that this -- if this hypothetical were to occur, that's why we've done light microscopy and FTIR and SEM after each of these steps to make certain that we're not doing it, to make certain this hypothetical did not occur and we didn't find it.

Q. Okay. And I understand that. But my question is, let's say you could get some of the sample that was not, you know, one of the knotted areas, and you were to take a pristine one and then one that had gone through, in theory, oxidized and then been cleaned. And if the oxidized cleaned one had a smaller diameter than the pristine one, could

that be evidence of degradation that had been removed?

A. I don't think you can use your hypothetical. Because you've got to remember that not only do you have knots, but you have tension on the fibers. And the exemplar right out of the package has not been anywhere other than through the extruder. And it hasn't been in the aqueous environment. It hasn't been pulled, no tensions on it. You can't -- they are so small. And the difference that would be made would be so small that you could not get an accurate measurement of that. This hypothetical will not work in real life.

Q. Okay. I just wanted your opinion on that. And I think what you said was, was maybe the diameter -- if that were to take place, the diameter would be somewhere around 130, and you would be looking at a reduction of -- I mean, 170, and you would be looking at a reduction of maybe three?

A. 2 to 3 microns.

Q. So it would be very difficult to measure that?

A. Oh, yeah. It would be very inaccurate. You couldn't use that as a technique. And that was -- we are all hypothetical here, aren't we?

Q. Yeah. I will go on record saying that you disagree with the underlying thought process. I was just getting your opinion on this.

A. Yes, sir.

Q. I know you do not agree that degradation takes place. You have told me that.

A. In fact, we've proven that case scientifically.

Q. I know you think you have.

A. It's all in the chemistry, and we will show you the chemistry before this is over.

Q. Well, you're showing me chemistry today. It's kind of good.

If you were going to give me a grade thus far, what would you give me? Would you give me an "A," or would I be more in the "C" range?

A. I would just have to say that I haven't had enough time with you before I grade you.

Q. Well, we'll see. I've got about an hour and a half or so or an hour. We'll see how I do. Maybe I can win you over at the end.

A. I kind of like you, actually.

Q. I like you, too.

MR. MONSOUR: We're at break time.

Since I've gone through that, let's take a

break. I've got one more hour with you.

(A BREAK WAS TAKEN.)

MR. MONSOUR: We're back on the record. Are you ready to continue, Dr. Thames?

THE WITNESS: Yes, I am.

BY MR. MONSOUR:

Q. You told me that thus far today it's all about science. It's all about the chemistry, right?

A. It's all in the chemistry, sir.

Q. So for the chemistry that you've talked about that goes all the way back to the 1940s, for that chemistry to take place, you've got to have formaldehyde?

A. Yes, sir.

Q. If there's no formaldehyde, then your opinions based upon formaldehyde would fail, correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: Well, they wouldn't be part of my opinions if I didn't have formaldehyde.

BY MR. MONSOUR:

Q. But I guess what I'm getting at is your opinions based upon the layer on the outside of the Prolene being the -- you know, the coating that is

created by formaldehyde and protein, that can only exist if that implant was put in formaldehyde, correct?

MR. HUTCHINSON: Object to form.

THE WITNESS: Well, it only exists because there's proteins there. Remember, the first thing that went to the foreign body was proteins, and that's collagen. And so the formaldehyde was added after that happened.

BY MR. MONSOUR:

Q. I understand the protein stuff. I guess what I'm getting at is, for what you're talking about, we've got to have formaldehyde?

MR. HUTCHINSON: Object to form.

THE WITNESS: You have to have formaldehyde to effect the chemical reaction that we've been describing that's on page 17. But that does not mean that you don't have strong adhesive bonds of proteins to the fiber without the fixation process. That has to be in place before the formaldehyde fixes it.

BY MR. MONSOUR:

Q. But I guess what I'm getting at is the --

again, going back to regular people language, --

A. Yes, sir.

Q. -- what you're saying is there is a coating on the outside of the Prolene fibers, which you do see, correct?

A. Yes, sir.

Q. And in pictures we see them. And that coating has cracks in it, according to you, correct?

A. Yes, sir.

Q. For that coating to form, you've got to have formaldehyde?

MR. HUTCHINSON: Object to form.

THE WITNESS: Not necessarily, no, sir. For the coating to form -- that forms as a result of fixation, you have to have formaldehyde. But if you don't have formaldehyde, you still have proteins, a coating formed around the explant. You still have that formation, but it's different in that it's not cross-linked with formaldehyde. It's still there.

BY MR. MONSOUR:

Q. Okay. So --

A. It's there before the formaldehyde is ever added, so you've got an adhered protein to this

fiber.

Q. So let's talk about that. We're going to talk -- this section of the deposition is going to be in situations where nothing was ever put in formaldehyde. Okay?

A. Okay.

Q. So let's take formaldehyde and throw it out the window.

If I get an explant and it's never been put in formaldehyde and there is tissue that is on that explant, what do I need to do to clean that one?

A. The same process will work. You will soften the flesh with water. You will use the sodium hypochlorite that will take the bleach off -- or the bleach will take the -- excuse me -- the excess tissue off. And if you use the same process, it will give you a clean explant.

Q. What is allowing the protein flesh to bind to the Prolene implant?

A. You remember we talked earlier about cohesion and adhesion? We had this discussion in the session before this. Well, there's a strong adhesive bond that forms between the proteins and Prolene, and that occurred -- in the last session,

that occurred even before formaldehyde was added. That's the point I'm trying to make.

If you have a strong bond already formed, when you add the formaldehyde, you're making it stiff because, i.e., you want to preserve it, number one, so that it doesn't rot; and if you're a histologist, you want to make sure that it's been fixed so that it's rigid enough that you can get a good slice and get you a good -- material to work with.

Q. Okay. Good.

So here's my next question. For the formaldehyde-protein bond that you explained to me, you were able to cite me some articles from the '40s with Dr. Fraenkel-Conrat. Is there any authority that explains the bond that forms between the Prolene and the protein?

A. Yes, sir. And I have several of them cited in this report, in the reports that you see.

Q. So those are cited in the report?

A. Yes, they are.

Q. Could you very quickly point me to which section that is?

A. It may not be very quickly.

Q. Assume I haven't memorized your report but

that I have read it.

A. 59 and 60, 61 and 62 on page 15 of my report.

Q. On page what?

A. 15 of my report. With your permission, I would like to read this first sentence.

Q. Please do.

A. It is under the heading of "Protein Adsorption on Implant Device Surfaces."

"It is well established that implantation of a foreign body (mesh materials, as an example) elicits a foreign body reaction involving the immediate formation of tenaciously adsorbed and thus adhered 'protein coating' onto the surface of the implanted materials," 59, 60, 61 and 62 references.

Q. And you cite -- there is a Dr. Kyriakides, and he's got a book. And there's chapter 5 of that book, and you're citing to that?

A. Yes, sir. It's important that we go -- to really be able to explain this, if you don't mind, it's important that we look at that a little closer. Is that okay?

Q. Sure.

A. Well, if we go down to about midway in that paragraph, it says, K-Y-R-I-A-K-I-D-E-S,

"Kyriakides also states that body proteins adsorb onto implanted material surfaces and contact the surface even before cells reach the implant," reference 64.

So you've got an implant, and then you've got the proteins, and then you've got the cells of the human body coming in. That's all there before we ever get to formaldehyde, because that's in the body. Then it has to be taken out of the body as an explant, put into formaldehyde, and then the formaldehyde reaction takes place.

Q. Okay. So with regard to this, this is the first bond that takes place. Then the -- I don't want to get the word wrong. Then the cross-linking takes place when the formaldehyde is added later?

A. Yes, sir.

Q. And I think I asked you this, but I'm not for sure. Which bond is stronger, the first bond that takes place, the adsorption -- that's "ad" with a "D" -- adsorption of the protein onto the polypropylene or the second one that takes place with the formaldehyde?

A. I have not measured that specifically, and I cannot give you a specific technical answer. But I can tell you based on the cleaning protocol and

the information that I've read, that the bond between the proteins and the -- and Prolene, which is the fiber, is very strong, as is the cohesive bond. They're both strong.

But in this cleaning process, we're working on the cohesive bonds, in other words, to make the bonds between the fibers break and go away so that we can move the materials off of the surface of the explant --

Q. Okay.

A. -- without damaging the explant.

Q. Another question I want to ask you, you talk about this, and you talk about the staining of some of Dr. Yakovlev's work when you talk about H&E stains, I guess, adhering to polypropylene.

Do you remember that?

A. No. H&E stains won't adhere to polypropylene.

Q. That's what you say in the report. You say it --

A. That's a fact.

Q. -- cannot happen.

A. It's all in the chemistry.

Q. Let me ask you this: Is there a chemical difference between polypropylene and oxidized

polypropylene?

A. Well, oxidized polypropylene would have an oxygen atom in it. It would be a ketone, more than likely. It would not be soluble in water. It would not have a functional group on it that would be attracted to or would react with the stain.

Q. So I guess you anticipated my question.

A. Yes, I did.

Q. My question is, can H&E stains, can they stain oxidized polypropylene?

A. I don't believe they will, no, sir.

Q. Now, you've said, "I don't believe they will." Where would we look for authority on that? Because I don't believe -- you know, I don't believe Texas is going to win the national championship next year. That doesn't mean they're not going to.

So when I hear, "I don't believe," my question is, where do I go for the authority as to whether or not H&E stains will stick to oxidized polypropylene?

MR. HUTCHINSON: Object to form.

THE WITNESS: Well, first of all, the term "stick to" is not technical and has no merit in this conversation, but we realize that you're just using it as an analogy.

BY MR. MONSOUR:

Q. Right. I'm using regular people words. You can use whatever words you want.

A. First of all, in order for something to adhere to a stain, it has to be ionic. It has to have an ionic bond. It has to have a structure if it's capable of being ionic. To be ionic, it has to be in water to form an ion, to be in an aqueous medium.

Polypropylene and/or oxidized polypropylene is not going to be soluble in water. It is not going to have a functional group on it that will ionize such that it can react with an ionic species of a different charge.

That's what happens when you get a stain to form a bond, adhere to it. That's why when you wash off all the excess stains, that stays there, because a chemical bond has been formed. And that's why the color comes in. Okay?

Q. Okay.

A. And you won't have those functional groups present if you oxidize polypropylene. And if you do, it will be of such a high molecular weight that it won't go into water and it won't be ionic and it won't stain.

And I use as my authority to back up my support the experiments of Dr. Steven MacLean from Exponent, and that's a very recent response. And they have proven that it doesn't stain. I know it wouldn't stain.

If you look at the chemistry and you look at what has to happen for a stain to adhere, to form a bond, you would know that this just will not stain.

Q. I'm just -- I know you seem incredulous that I couldn't know this. I'm not real good at chemistry.

A. I understand. But I'm just saying this for the record because it's a fact, you know.

Q. Who is Dr. Steven MacLean?

A. He's a scientist that works for Exponent. He's out in the San Francisco laboratory, and he submitted a report.

MR. MONSOUR: Is he one of y'all's retained experts? Is he a testifier?

MR. HUTCHINSON: (Nods head affirmatively.)

BY MR. MONSOUR:

Q. What would you need to see, what type of evidence would you need to see to -- so that it

could establish to you that polypropylene or Prolene degrades once it's implanted in a woman transvaginally?

MR. HUTCHINSON: Objection. Asked and answered.

THE WITNESS: I have answered that question before.

BY MR. MONSOUR:

Q. Okay.

A. You asked that question. And I'm not being short with you, but you asked it, and I gave you the answer.

Q. Okay. I forget.

A. I would need carbonyl groups formation. I would then follow up with that molecular weight physical property test.

Q. Okay, okay. As far as cleaning explanted medical devices and prostheses, is there any textbook or authority that you would rely upon?

A. Well, first of all, the only medical device that I was interested in cleaning was Prolene, not anything else.

Q. Okay.

A. So when you look at Prolene, you look at a fiber, you look at the fact that it has a melting

point, you look at the fact that it softens, and you are saying, well, I'm going to be looking at this because people are going to be asking me, well, does this material oxidize or not? That's the key question. Does it oxidize? Does it degrade? Should it be in the human body? And I've got to find out whether that's the case or not.

So I select a protocol understanding the chemistry of where that explant came from. See, I look at it in totality. Where did it come from? It came from the human body. Well, what's on it? Flesh. Well, what else? Well, when they got through taking it out, they dropped it in some formaldehyde. And guess what? Flesh has proteins in it, and proteins react with formaldehyde, and it forms a hard matrix around it. I've got to get that off. But I don't want to do anything to damage the implant. How do I do that? Well, I just reverse the reaction that caused it to form in the first place, and then I use a little Clorox along the way to get the flesh out of the way.

And when I do that, after every step I look at the light microscopy, I look at the scanning electron microscopy, and I look at an FTIR to see if there are any carbonyl groups there. If there are

no carbonyl groups there, then there's no oxidation.

Q. That's one of the things I was going to ask you about. And this is -- again, this is going to go back to my ignorance in chemistry.

But when you were talking about looking -- using FTIR to spot carbonyl groups at the 1730, 1750 range, do you remember us talking about that?

A. I do, sir.

Q. And you said when you find it and it becomes positive, one of the things that it could be positive for, if it was there, is it could be for degraded polypropylene, but it could be for maybe calcium stearate or for DLTDP, right?

A. Yes, sir.

Q. Are there amounts of those components that you would need to see for it to show up on FTIR?

A. Well, I haven't done a study where I say, okay, Ethicon, I want you to make Prolene with .1 percent by weight of DLTDP and then by .2 percent by weight and then .3 percent by weight.

In order to answer your question and be very precise, I would need to know that. All right. And, of course, after each of those, I would look at the FTIR.

But I have found DLTDP and FTIRs of

exemplars and found that as we clean them, that diminishes somewhat because we're using bleach and we're using water.

So I can't give you a specific technical answer to your question.

Q. Okay. So let me ask you this: Why as you use bleach and water do you think there would be less and less DLTDP?

A. Well, it would be oxidized.

Q. What's "oxidized"?

A. The DLTDP, and hydrolyzed. It's an ester.

Q. Okay.

A. Esters hydrolyze in water.

Q. And so the water is causing the DLTDP to oxidize?

MR. HUTCHINSON: Object to form.

THE WITNESS: The water and the environment it's in is causing a reduction in the concentration of DLTDP.

BY MR. MONSOUR:

Q. And DLTDP is an antioxidant, right?

A. Yes, sir.

Q. So I just want to ask my question clearly. You kind of answered it, but I want to make sure I get this clearly.

How much DLTDP needs to be in a Prolene fiber for it to show up on FTIR?

A. I've answered that question.

Q. And the answer is you don't really know?

A. No, I don't. Because I haven't done a quantitative measurement to know exactly the amount that needs to be there before I will pick it up on my FTIR instrument.

Q. Right. But then that gets back to my question. Wouldn't you need to know that? Because what I -- you're trying to teach me good science, and I'm wanting to be a good student here. I want an "A." I want an A-plus.

A. You better hurry.

Q. I'm wanting an A-plus.

So my question is, if you're kind of ruling in as a possible that DLTDP could be what's making the FTIR show up between 1730 and 1750, wouldn't you need to know as a scientist how much DLTDP would have to be there for it to ping positive?

A. Well, that would be helpful. But at the same time, what we see happening as we clean this is that DLTDP is lost, and there's still no carbonyl groups. And that's not -- and it doesn't show up in

every one of them, by the way.

We're talking here like there's an assumption that every one of these fibers shows DLTDP, and it doesn't.

Q. Okay.

A. But what should be present, if we have oxidized polypropylene, is we should always have a carbonyl peak, and that carbonyl peak should not go away in this cleaning process.

Q. All right. Let me ask you about a calcium stearate.

A. Yes, sir.

Q. How much calcium stearate would need to be present in a Prolene strand so it could, you know, show positive on FTIR between 1730 and 1750?

A. Same answer that I gave you for DLTDP.

Q. And the answer to that is you're not really sure, correct?

A. That's correct from a very specific point of view.

Q. So tell me, what is the purpose of DLTDP? Tell me what an antioxidant does.

A. Well, if there's a free radical formed, the oxi- -- the theory is that free radicals are formed, and then they form hydroperoxides, and they

decompose. And then the decomposition process, it breaks the bond of a Prolene species and produces a ketone or an aldehyde. And that's where a C=O would be made during the oxidation process. And that's what we should be seeing occurring on the explant fibers when we look at it in our FTIR.

Q. So let me ask this question. Prolene is a polypropylene that has had antioxidants added to it, right?

A. Correct, and some other things.

Q. If you took just pure polypropylene without the additives, would it degrade through oxidative degradation?

A. It depends upon how much -- how you did the degradation. All of this is, what did you subject the material to? It's well known that polypropylene will degrade in thermal energy. You know, it has a -- it starts degrading at 333 degrees Centigrade, which is 600-and-something degrees Fahrenheit. Well, that's an unrealistic number for what we're talking about here.

Q. Right, absolutely.

A. It's also known that UV light will degrade polypropylene even more readily than energy. So polypropylene will degrade, and I've said that

clearly in my report.

Q. Okay.

A. But what we're talking about is, does it degrade in the environment that we're talking about? And the answer is "no."

Q. What about when it's exposed to reactive oxidative species?

A. Well, that's been a --

MR. HUTCHINSON: Excuse me. Object to form. Are you talking about Prolene or polypropylene, Counsel?

MR. MONSOUR: Prolene.

THE WITNESS: Thank you. That's the way I understood you to mean.

No one has determined or made a determination of the fact that reactive oxidative species oxidizes polypropylene, to my knowledge. I have not seen that anywhere. I know that has been thrown out as a hypothetical, but it's never been proven.

BY MR. MONSOUR:

Q. Okay. So let me ask you this: What would you need to see to have it established to you that reactive oxidative species could cause degradation in either Prolene or another polypropylene that had

antioxidants added to it?

A. Well, the question that you asked me broadens out the concepts of what we're talking about here.

When you're saying, well, what would I need, the implication is, is there some kind of test that you could run that would satisfy you that reactive oxidative species will oxidize Prolene. Well, we're talking about an accelerated test in an environment that Prolene is not in.

The only way to do what you're talking about is to have Prolene in a human body or in an animal where there's excessive reactive species and then evaluate the explant as it's removed. Otherwise, we're talking about an accelerated test, a different environment. And I don't know how you achieve that.

I mean, I know that Dr. Priddy has tried accelerated tests, and they don't work. And the reason is there's what's called a transition state, and the transition state is if you start out with two species, A and B.

In our case, those two species would be reactive oxidative species and Prolene, and they're hitting each other. They're there. The chemicals

react. But what happens as a result of their contact? In order for us to produce, as you want to say, a carbonyl group, there's a certain amount of energy that is required to go up to the transition state before it can go into the final products over here.

And I have not seen any case where there's been any carbonyl group formation. And, therefore, I don't ever think the activation energy required has been reached. No one has shown that.

Q. When you look at explants and the level of DLTDP has dropped or has lessened, does that indicate to you that the antioxidant is working as it's intended?

A. Well, when you say when I look at an explant, keep in mind that what we're doing is we have one small piece of fiber, and it's round and that we're putting a light through it. And sometimes that light beam may be on the -- this is -- I'm taking a bottle and laying it on its side. If the light beam comes and hits over here, then the transmission is a shorter wavelength. If it hits here -- excuse me. It hits through more of the material than if it's over here.

And it depends on the orientation

sometimes as to whether you see DLTDP or not. That doesn't mean it's not there. Okay?

Q. Okay.

A. So...

Q. No, I guess that's not my point.

My point is, are you basically saying that the DLTDP is functioning as an antioxidant with regard to light?

A. Yes.

Q. Okay.

A. And in the body, in a person's body, as we're talking about here, it's an antioxidant and a very good one.

Q. Was the -- and you might not know the answer to this. Was the antioxidant package for Prolene, was it designed for -- were the antioxidants selected based upon needs for implantation in the human body or needs based upon thermal processing? Do you know?

MR. HUTCHINSON: Objection. Speculation.

THE WITNESS: Oxidation is oxidation, but it just depends on what it means. You can have a product designed for high energy. And that's one of the things that Santonox R

was put in for, because it's more for processing than -- you have to put polypropylene under a pressure to extrude it out of the extruder, and it has to be at high energy so it's melted. And you don't want it to oxidize there. So it's there as well as is DLTDP.

So they're put there, number one, to make certain that during the processing stage you don't get oxidation. And my logic would be, well, certainly, if you don't get oxidation during that processing stage, how would you expect to ever get it in the human body? You just think about that from a simplistic point of view here.

BY MR. MONSOUR:

Q. That's what I've got to do. You can't make it too hard or I'll be all confused.

A. Well, here you've got this extruder, and I'm holding this bottle up, and you're pushing the Prolene, the polypropylene, not pro- -- all right. You're pushing it through and -- but it does have the materials in it that make it Prolene. And you're pushing it through, and it's under high energy, and it's in a very flexible state. Oxygen

is all around it, but it doesn't oxidize.

Why in the world would it, if it doesn't oxidize there, would it oxidize in the body with a reactive oxidative species present?

Q. Well, let me ask you this: Do they ever look at polypropylene that's pristine to see if there's any degradation on the outside of it to -- through the processing of it?

MR. HUTCHINSON: Object to form.

THE WITNESS: Well, let me answer that this way. I have looked at many, many exemplars of polypropylene, and there's never been any oxidation on the surface of it.

BY MR. MONSOUR:

Q. What have you looked for?

A. To see what it looked like. To give a control spectra. It's a control.

Q. Hold on. I think I read something that talks about that. Dr. Thames, I could swear I saw something about this.

What's "melt spinning"?

A. You melt it and you spin it into a fiber.

Q. Is that different than -- is that how they do Prolene?

A. They extrude Prolene, and it comes out as

a fiber.

Q. So Prolene is extruded?

A. Yes, sir.

Q. And melt spinning is a different process?

A. That's my understanding. You could melt spin the fiber. You could do that, and I'm not sure whether they do that or not, but it could be done.

Q. How would you -- I'm going to ask you some questions while she's reading through that.

You do not believe there is any pristine, new Prolene or polypropylene with additives fibers, as they're extruded, you don't think there would be any surface oxidation at all?

A. No, sir. Well, let me back up. When you said "at all," I can't say there's not one molecule of oxidation. But for practical purposes, there is no oxidation, and I'll tell you why.

I know this. Every piece of Prolene that I've looked at, and I've done all the exemplars, it has never had any oxidation on the surface. So what they're selling for implantation in human beings doesn't have oxidation on the surface.

Q. Now, does Prolene have any antioxidants other than Santonox R and DLTDP?

A. No, sir.

Q. Just those two?
A. Yes, sir.
Q. And they're both intended or used for thermal processing?
A. Yes. Santonox R is primarily used to be there for the thermal processing, and DLTDP is there for that as well. They both are UV inhibitors -- or antioxidants. Excuse me.
But the principal one during the spinning process or melting process -- extruding process, I mean, is Santonox R.
Q. Okay. Do you know a Dr. Guidoin?
A. Robert?
Q. Yeah.
A. I don't know him, but I know him by his involvement. I'm not sure if he's still alive or not. I don't know. But I do know him by his involvement here. He's the one I referenced that did the paper on the difficulty in removing everything. So, in that regard, yes, I know him.
Q. And he has also done some testing on some Prolene explants over the -- or been involved to some extent?
A. He's provided -- I know he provided a lot of explants to Ethicon for them to test, and they

did so as they received it as is, if you remember.

Q. Do you know how he cleaned the explants?

A. I'm not sure.

Q. Would you look at his cleaning techniques as being authoritative?

MR. HUTCHINSON: Object to form.

BY MR. MONSOUR:

Q. Or reliable?

MR. HUTCHINSON: Same objection.

THE WITNESS: I don't know what his cleaning technique is, other than maybe washing it in sodium hypochlorite. I have not seen a technique that he's put together like the one I have here. I just know what his article said and how he felt the difficulty in cleaning them was.

And I do know that the explants that he has provided to Ethicon were labeled "as is" implication; therefore, they have not been cleaned and been through a cleaning process like this. And, of course, the data that was achieved from the people who evaluated those "as is" implants showed there were fibers fleshed out.

BY MR. MONSOUR:

Q. Are you talking about the dog study?
A. No.
Q. Which one are you talking about?
A. That's not necessarily a study. But they were looking at -- "they" being Ethicon -- was looking at a lot of explants to look at this issue of, well, people are saying maybe we've got some oxidation here. Is it happening? And then the answer is "no."

And they were looking at all sorts of implants to determine whether there had been oxidation and could prove it was there. And the answer was "no." And he provided them a lot of explants. And when he provided it to them, it was labeled -- and they said, "Well, we will evaluate it 'as is,'" meaning here it is. I'm not going to do anything to it.

And when I see something that is "as is," okay, there it is. I'm going to evaluate it like it is.

Q. The dog study you're familiar with, correct?
A. I am. Yes, I am.
Q. Your counsel really likes the dog study.
A. I do too.

Q. Tell me why you like the dog study so much.

A. Well, it's a seven-year study. The beautiful part of it is it was set out to determine exactly what we're talking about today. Do we have oxidation taking place? Do we have damage to the implants taking place?

Let's go to like -- and, you know, you asked me earlier how I would go do certain things. And I said I would have to put it in a human body or in an animal and evaluate it over a long period of time so that we could see what kind of reactive oxidative species were really there.

Well, as they did the dog study, at intervals they would take a dog and euthanize it and take the sutures out, the Prolene sutures, and they would evaluate it. Then the evaluation that I really liked was they would do the mechanical study. They would do the tensile strength, elongation, and then you could look at toughness. They also did molecular weights.

And what I described to you earlier is that in order to have degradation, you've got to have loss of molecular weight, and you've got to have loss in mechanical/physical properties.

There's no question about that. That is not an argument. It's written in every paper you'll get to, every scientific document. It's not Shelbyism; it's scientism.

Q. Okay.

A. So they did that, and they did that in intervals. And when they finally got -- and every time they were doing the molecular weight, molecular weight, molecular weight, tensile strength, tensile strength, tensile strength, elongation. And they got all of that data, and they plotted it.

Do you know what they found out? They didn't have any loss of molecular weight after seven years. And they also found out that the implants -- that the Prolene improved toughness over that seven-year time, so they got stronger and tougher.

So that would not be the case under any circumstances had there been degradation to cause molecular weight loss. You would never have gotten those kind of results.

Q. Okay. Now, you had mentioned some ASTM testing that was done before --

A. Uh-huh (affirmative response).

Q. -- where you have to have five samples.

A. Yes.

Q. How many samples did they have in the dog testing?

A. My understanding is they used the ASTM testing. They used five multiple samples.

Q. So they did have five?

A. That's my understanding.

Q. As far as the loss of -- there not being a loss of molecular weight in the dog study, do you know how they measured that?

A. GPC. As a matter of fact, one of your witnesses has done about almost 20 GPC analyses of explants and found no loss of molecular weight.

Q. Who is that?

A. Dr. Jordi. And, of course, these gentlemen at Ethicon did their molecular weights. And he has testified that there was no loss in molecular weight.

Q. Is there any other way to measure a loss of molecular weight other than GPC?

A. Well, that's considered the gold standard. And why would you go away from the gold standard?

Q. I don't know, unless there's a platinum standard.

A. No, huh-uh. We're talking about the gold standard here.

Q. A diamond standard? I don't know.

A. Well, plants sometimes use viscosity measurements as -- they'll run a series of tests where we're going to make this polymer, and this polymer has to have a certain viscosity if it's maintained its molecular weight and so forth.

And so they'll do their control, their quality control based on viscosity because it's a lot easier, a lot simpler to run viscosity measurements than it is GPC measurements. But those viscosity measurements were determined by GPC measurements early on.

Do you follow me?

Q. No.

A. Okay. Before they made a determination on what a viscosity needed to be to produce a product that they wanted to have the properties that they wanted to have, they had to first determine, well, what is the molecular weight at this viscosity, at this viscosity, at this viscosity? And so they determined that at viscosity you had a certain molecular weight. And they measured it based on that, on the viscosity.

If the viscosity is too high or too low, the one they pinpointed, then they need to change

the -- you know, their system is out of control, and then you get it back in control. That's the quick way to do it. That's the way a production plant might do it.

Q. Okay. Toughness, --

A. Yes, sir.

Q. -- it's been mentioned with regard to the dog study. And I think you've got a section in your report about that.

How do you measure toughness, and how did they do it in the dog study?

A. Well, toughness is the area under the curve when you have tensile strength and elongation measurements. Let's get back to this. Let's go show you that. I'm not sure what page that's on, but we'll try to -- I think it should be fairly early in the report.

Q. I think it is. That is page 8.

A. Yes, sir. If you see that -- the vertical axis is breaking strength. It's called tensile strength. And what they're doing is they're taking this material and putting it in an MTS, a strand of fiber. And they're pulling it, and they're pulling it at a certain speed, and it ultimately breaks. When it breaks, that's ultimate tensile strength,

and that's what they're measuring.

Well, while they're pulling it to break it, they also are elongating it, and they're measuring elongation at the same time. So they get these two numbers, and they plot them. Elongation is a function of tensile strength.

And you'll notice the red part. This was the -- this is the control at year zero. Okay? Elongation at 1.6 pounds is 37 percent. That's tensile strength. The tensile strength is 1.68 pounds that they had when it finally broke.

You see your chart right here?

Q. So it breaks here?

A. Right here.

Q. Right there?

A. Yes, sir. And this line just goes down to show you --

Q. Where it is?

A. -- where it is.

Q. Okay.

A. And then the same thing is while you were putting that much force on the fiber, it was elongating over here to after year seven -- well, in this case, the elongation was 37 percent, and this is the tensile strength.

Q. So if I look at this chart, basically what it shows is the control versus the year seven --

A. Yes, sir.

Q. -- one, it was -- it looks like the break strength from the control to year seven dropped a little bit, from like 1.65 to 1.7 down to 1.6, right?

A. 1.68 is the pounds.

Q. Okay. 1.68 --

A. To 1.6.

Q. -- to 1.6. But the elongation increased from 37 to 78.

A. That's correct.

Q. So the area underneath the curve, the blue curve, versus the area underneath the red curve is the toughness. And you're saying that because the area underneath the blue curve is so much bigger, it's tougher than the area underneath the red curve?

A. That's how it's measured, yes, sir.

Q. Now, here's my question. Can you explain to me how that could happen?

A. Yes, sir, I absolutely can. When you implant polypropylene into a human body, it is surrounded by tissue, which is made up of fats and oils, triglycerides. You know, we go get our blood

tested to see how much triglycerides, how much cholesterol we've got in our body. So we know they are there. And these are materials that are lower molecular weight, and these are materials that have an affinity for something like Prolene because it's a hydrocarbon material. And they function and they move into Prolene, and they become plasticizers.

A plasticizer is a material that will allow something to be more pliable. And for the young lady over here, sometimes you use hand cream because your hands have gotten a little dry and you're afraid they will crack and you don't want that. You want your hands to look supple and soft. So you use hand cream, which is a plasticizer, which moves into your hands and plasticizes your skin, and it becomes very soft. In our case, that's exactly what happened.

And then when you talk about pulling strings this way, if you just think about it from a very simplistic point of view now, simple, you wanted me to talk simplicity, if you took -- those materials are acting as lubricants for the fibers. So if the lubricant is not there, it will pull and pull and then snap. That's the first elongation case.

But after implantation and the plasticization of the environment, you've got the elongation. So, actually, from a functional point of view, it improved over time.

Q. Kind of like if you put boot cream on Red Wing boots?

A. Absolutely. They're hard as a rock, and you want to make them softer.

Q. Okay. I'm going to ask you a couple more questions on plasticization, and then I'm going to be done.

A. Okay.

Q. Now, as far as your theory on plasticization --

A. Well, it's not my theory.

Q. Okay.

A. This is well established. The concept of plasticization is well established.

Q. Let me ask you this question.

A. All right.

Q. Let me ask this question, then. In the dog study, that was a study done by Burkley.

A. Yes, sir.

Q. B-U-R-K-L-E-Y.

Did Dr. Burkley conclude that oxidative

degradation took place?

A. He indicated that there might be some oxidative degradation, and he was wrong. Because if there had been, you would not see a curve like this. It's impossible to have oxidative degradation and have that curve of physical properties and no loss in molecular weight.

Q. Okay.

A. They go together. It's like being married and having your first child. You know, carbonyl group formation, loss in molecular weight and physical properties, they all go together.

Q. I'm going to quote you later on about that for a point that I frequently made.

But I would like -- so Dr. Burkley -- did Dr. Burkley ever conclude that plasticization had taken place?

A. I don't think he referred to plasticization, as far as I can remember.

Q. Did he ever refer to anything similar to plasticization?

A. Not that I can remember.

Q. Did he ever refer to increased toughness?

A. Not that I can remember.

Q. Okay. So I'm just going to ask you this,

and you might not know the answer.

A. Okay.

Q. But Dr. Burkley has got all this data in front of him, and he's specifically there looking to see whether or not there's oxidative degradation, correct?

A. That's correct.

Q. I mean, that's the whole point of his tests, right?

A. Uh-huh (affirmative response).

Q. Right?

A. Correct.

Q. If that's the point, and the issue of -- or plasticization is well known, and toughness is well known, and he's got all the data in front of him, how did he not get to where you got?

MR. HUTCHINSON: Objection. Speculation.

THE WITNESS: He was a very young scientist at that time, and I'm not sure what his polymer background was.

BY MR. MONSOUR:

Q. Is it a fair statement for you to say -- I want to summarize your opinion and see if you agree with me.

Dr. Burkley had all the data he needed. He just missed it and misinterpreted it?

A. This is no reflection on Dr. Burkley, but yes, that's the answer.

MR. MONSOUR: Okay. I have used up my three hours. I am done with your general deposition at this point in time.

EXAMINATION

BY MR. HUTCHINSON:

Q. Dr. Thames, Chad Hutchinson, counsel for Ethicon. I have a couple follow-up questions.

If you'll turn with me, please, to page 100 of your report, this is your general report; is that right?

A. That is correct, sir.

Q. If you look on page 100, it shows the cleaning protocol that you were asked about; is that right?

A. That's correct.

Q. Under the cleaning protocol, it states, "Figure 33, Patient 4 Cleaning Protocol."

Did I read that correctly?

A. You did, sir.

Q. Now, Dr. Thames, is patient 4 part of the 20 case-specific reports?

A. No, sir.

Q. Dr. Thames, does the title under the cleaning protocol on page 100 say, "This is the exact protocol that was used with all 20 case-specific explants"?

A. Where are you looking at?

Q. (Indicating.)

A. No, sir.

Q. And do the case-specific reports that you did now include the correct cleaning protocol that was used with those plaintiffs?

A. Yes.

Q. Dr. Thames, is there anything at all wrong about this cleaning protocol?

A. Not at all.

Q. Is it just an example of an older cleaning protocol that you have used on what we have called patient 4?

A. Absolutely.

Q. And, in fact, are you giving patient 4 as an example of an explant that has been cleaned here in your report?

A. Yes.

Q. And did you provide some images from patient 4?

A. I did.

Q. And if you're giving patient 4 as an example of an explant, wouldn't you want to show the cleaning protocol that you used for that explant?

A. I would.

Q. And is that what you were doing here on page 100?

A. Yes.

Q. Did it work on patient 4?

A. Yes, sir.

MR. HUTCHINSON: I don't have any further questions.

MR. MONSOUR: A real quick follow-up.

FURTHER EXAMINATION

BY MR. MONSOUR:

Q. Was the protocol that you used that's on page 100 of your report, was that done to clean protein and flesh off of a Prolene implant?

A. Yes, sir.

Q. Was it done in connection with the transvaginal mesh litigation?

A. Yes, sir.

Q. Would you remember the name of the patient off the top of your head?

A. Yes, sir.

Q. Who was it?

A. Ramirez.

MR. MONSOUR: Okay. That's all I have.

MR. HUTCHINSON: Just one quick question.

FURTHER EXAMINATION

BY MR. HUTCHINSON:

Q. Dr. Thames, you were asked questions about seeing that DLTDP is lost during the cleaning process.

A. Yes, sir.

Q. Do you remember that?

A. I do.

Q. Why?

A. Why would it be lost?

Q. Correct.

A. If it's lost, it's lost because of the cleaning process itself. It's under temperature.

DLTDP is an ester. Esters will hydrolyze. This is 70 degrees Centigrade in an aqueous environment, and you have sodium hypochlorite in portions of that. And that is an environment that will hydrolyze esters and would certainly not be in the body.

It wouldn't be in the body. There's no

70 degrees in the body, and there's no sodium hypochlorite that we've added in the body.

MR. HUTCHINSON: Okay. Thank you.

(CONCLUDED AT 11:45 A.M.)

CERTIFICATE OF COURT REPORTER

I, Amy M. Key, CSR, and Notary Public in and for the County of Lamar, State of Mississippi, hereby certify that the foregoing pages, under penalty of perjury, contain a true and correct transcript of the testimony of the witness, as taken by me at the time and place heretofore stated, and later reduced to typewritten form by computer-aided transcription under my supervision and to the best of my skill and ability.

I further certify that I placed the witness under oath to truthfully answer the questions in this matter under the power vested in me by the State of Mississippi.

I further certify that I am not in the employ of or related to any counsel or party in this matter, and have no interest, monetary or otherwise, in the final outcome of the proceedings.

Witness my signature and seal this the _____ day of_____, 2016.

_____

AMY M. KEY, CSR

My Commission Expires June 19, 2016

SIGNATURE OF WITNESS

I, _____, do solemnly swear that I have read the foregoing pages and that the same is a true and correct transcript of the testimony given by me at the time and place hereinbefore set forth, with the following corrections:

PAGE:	LINE:	SHOULD READ:	REASON FOR CHANGE:
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

_____
(SIGNATURE)

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public